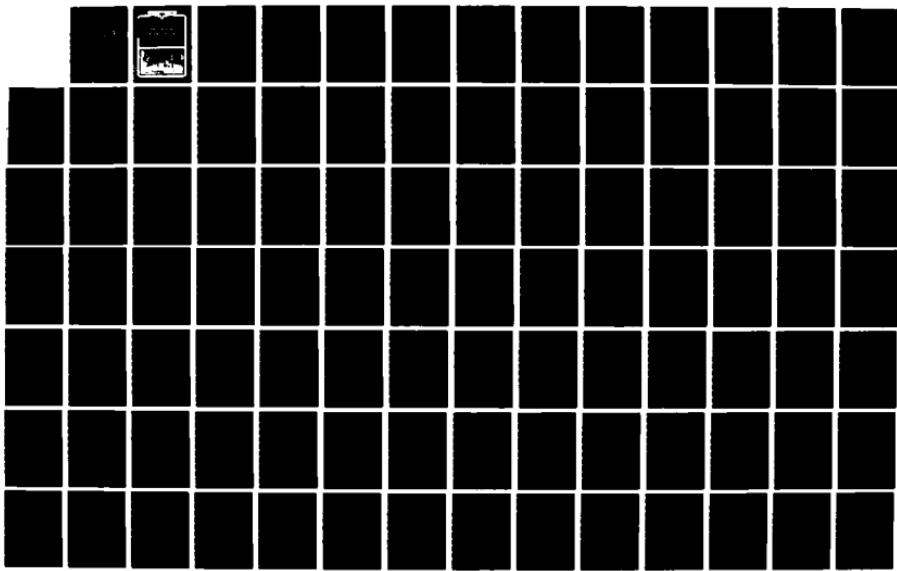
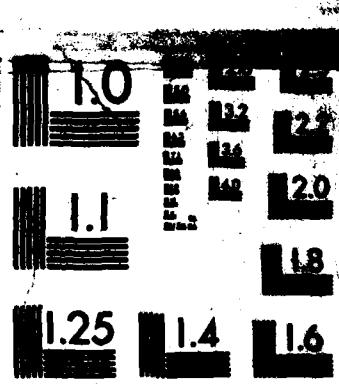


AD-A157 443 DEPARTMENT OF CLINICAL INVESTIGATION ANNUAL RESEARCH 1/2
PROGRESS REPORT FISCAL YEAR 1984 VOLUME 2(U) BROOKE
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DEPARTMENT OF CLINICAL INVESTIGATION

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|---|---|---|
| 1. REPORT NUMBER RCS MED-300 (R1) | 2. GOVT ACCESSION NO. <i>A157493</i> | 3. RECIPIENT'S CATALOG NUMBER |
| 4. TITLE (and Subtitle) ANNUAL RESEARCH PROGRESS REPORT <i>Volume 2</i> | 5. TYPE OF REPORT & PERIOD COVERED ANNUAL - FY 84 | |
| 7. AUTHOR(s) JAMES H. ANDERSON, JR., M.D. Lieutenant Colonel, MC | 6. PERFORMING ORG. REPORT NUMBER | |
| 9. PERFORMING ORGANIZATION NAME AND ADDRESS Department of Clinical Investigation Brooke Army Medical Center Fort Sam Houston, Texas 78234-6200 | 10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS | |
| 11. CONTROLLING OFFICE NAME AND ADDRESS Commander Brooke Army Medical Center Fort Sam Houston, Texas 78234-6200 | 12. REPORT DATE 1 October 1984 | |
| 14. MONITORING AGENCY NAME & ADDRESS (if different from Controlling Office) Office of the Surgeon General Department of the Army Washington, D.C. 20314 | 13. NUMBER OF PAGES 460 | |
| 15. SECURITY CLASS. (of this report) <i>Unclassified</i> | | |
| 16. DISTRIBUTION STATEMENT (of this Report) APPROVED FOR PUBLIC RELEASE; DISTRIBUTION UNLIMITED | | |
| 17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report) n/a | | |
| 18. SUPPLEMENTARY NOTES The findings in this report are not to be construed as an official Department of the Army position unless so designated by other authorized documents. | | |
| 19. KEY WORDS (Continue on reverse side if necessary and identify by block number) Clinical Investigations, all medical specialties Publications, presentations Detail Summary Sheets (Study Objective; Technical Approach; Progress; Status) | | |
| 20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Subject report identifies the research activities conducted by Brooke Army Medical Center investigators through protocols approved by the Clinical Investigation Committee, the Institutional Review Board, and the Animal Care Committee and registered with the Department of Clinical Investigation during FY 1984. Report also includes known presentations and publications by the Brooke Army Medical Center staff. The research protocols described were (continued on reverse side) <i>file</i> | | |

Block 20. Abstract

conducted under the provisions of AR 40-38, Clinical Investigation Program; AR 40-7, Use of Investigational Drugs in Humans; USAMRDC 70-25, Use of Volunteers as Subjects of Research; HSC Reg 40-23, Management of Clinical Investigation Protocols and Reports; and BAMC Memo 40-98, Department of Clinical Investigation, to insure the medical well-being, preservation of rights and dignity of human subjects who participated in these investigational studies. Research studies involving the use of laboratory animals were conducted under the provisions of AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs.

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| POG 8370 | Evaluation of Responses and Further Determination of Toxicity of Dibromodulcitol (DBD) in Children with Solid Tumors and Recurrent Brain Tumors Unresponsive to Standard Therapy, Phase II. (O) | 423 |
| POG 8461 | Protocol for Initial Induction Failures in Childhood Acute Lymphoblastic Leukemia. (O) | 424 |

Detail Summary Sheet

Date: 5 Nov 84 **Proj No:** A-1-84 **Status:** Ongoing
Title: A Pilot Study Using the HeNe Laser to Enhance Healing of Hematomas.

| | |
|--|--|
| Start Date 6 Feb 84 | Est Comp Date: |
| Principal Investigator Debra J. Krikorian, Ph.D., CPT, MSC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Clinical Investigation | Associate Investigators: Steven Stratton, Ph.D., CPT, AMSC Terry Nemmers, M.P.T., M.S., MAJ, AMSC Michael Hartshorne, M.D., MAJ, MC Wendy Blomgren, SP5 |
| Key Words: Hematoma Laser, HeNe | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 900.00 |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): To test the effectiveness of treating severe hematomas with The Helium Neo Laser (HeNe Laser).

Technical Approach: The right lateral thighs of rats were gravitationally traumatized yielding full thickness hematomas. Experimental animals were treated with an HeNe laser (632.8 nm) over a 10 day period and their lesions compared to those of untreated animals. Hematomas were visualized histologically and by ^{67}Ga gamma scans.

Progress: Another series of ^{67}Ga scans need to be completed and analyzed in order to obtain a good statistical analysis. Currently analyzed data implies tendencies towards enhanced healing in the laser treated animals but further analysis of the histological data will be required to confirm this observation.

Detail Summary Sheet

| | | |
|--|-----------------|--------------------|
| Date: 31 Oct 84 | Proj No: A-2-84 | Status: Terminated |
| Title: The Eyelids Role in Intraocular Pressure. | | |

| | |
|--|---|
| Start Date 13 Mar 84 | Est Comp Date: |
| Principal Investigator Henry L. Milne, III, M.D., CPT, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Surgery/Ophthalmology | Associate Investigators: Donald D. Bode, M.D., COL, MC |
| Key Words: Intraocular pressure | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): To determine if there is a correlation between intraocular pressure and eyelid constriction on the globe.

Technical Approach: Silicone was injected into the lids of two rabbits temporarily increasing the intraocular pressure.

Progress: The pressure normalized within hours. Since the theory was disprove, the protocol was terminated.

Detail Summary Sheet

Date: 31 Oct 84 Proj No: A-3-84 Status: Ongoing
 Title: Bladder Surface Mucin - Impact on Implantation of Transitional Cell
 Carcinoma II: Use of Standard Urologic Irrigants for Mucin Removal.

| | |
|---|---|
| Start Date 13 Mar 84 | Est Comp Date: |
| Principal Investigator Ian M. Thompson, M.D., CPT, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Surgery/Urology | Associate Investigators: William Gregory, SP5 Wendy Blomgren, SP5 |
| Key Words: Carcinoma, transitional cell Bladder surface mucin | Edward J. Shumski, M.D., LTC, MC C. Ritchie Spence, M.D., COL, MC |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | CMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): To determine if presence of bladder surface mucin and/or artificial reconstitution thereof prevents implantation of transitional cell carcinoma of the bladder after mucin removal with standard urologic intravesical irrigants.

Technical Approach: Animals are randomized to receive either heparin prophylaxis or saline control to attempt to prevent adherence and growth of intravesically-implanted transitional cell carcinoma.

Progress: The initial two trials of implantation were stymied due to animal facility atmospheric control and all animals died. A more recent study demonstrated no difference between treatment groups. It is anticipated that the study will be repeated with increased mucosal mucin reduction in an attempt to increase tumor implantation in control groups.

Detail Summary Sheet

Date: 31 Oct 84 Proj No: A-4-84 Status: Ongoing
Title: Radiation Therapy and Synergism with Chemotherapy for Treatment of
Transitional Cell Carcinoma of the Bladder.

| | |
|---|---|
| <u>Start Date</u> 3 May 84 | <u>Est Comp Date:</u> |
| <u>Principal Investigator</u> Ian M. Thompson, M.D., CPT, MC | <u>Facility</u> Brooke Army Medical Center |
| <u>Dept/Svc</u> Department of Surgery/Urology | <u>Associate Investigators:</u> William Gregory, SP5 Wendy Blomgren, SP5 Clayton L. Hadick, D.V.M., CPT, VC Madahava Baikadi, M.D., MAJ, MC C. Ritchie Spence, M.D., COL, MC |
| <u>Key Words:</u> Carcinoma, transitional cell | |
| <u>Accumulative MEDCASE</u> <u>Cost:</u> | <u>Est Accumulative</u> <u>CMA Cost:</u> 714.00 |
| <u>Number of Subjects Enrolled During Reporting Period:</u> | |
| <u>Total Number of Subjects Enrolled to Date:</u> | |
| <u>Date of Periodic Review</u> | <u>Results</u> |

Objective(s): To investigate the therapeutic effects of external beam radiotherapy and its possible synergism with chemotherapeutic agents in the therapy of murine transitional cell carcinoma.

Technical Approach: Two separate studies will be performed which will study the effect of radiation therapy for post-excisional treatment of transitional cell carcinoma.

The second study will investigate the effect of radio-sensitizers and cytoxin in the treatment of established murine transitional cell carcinoma.

Progress: This study has not been started.

Detail Summary Sheet

Date: 31 Oct 84 **Proj No:** A-5-84 **Status:** Ongoing
Title: Effect of Synthetic Sutures on Pelvic or Intraperitoneal Adhesions.

| | |
|--|---|
| Start Date 5 Jun 84 | Est Comp Date: |
| Principal Investigator Richard K. Cardenas, M.D., CPT, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Obstetrics-Gynecology | Associate Investigators: Clayton L. Hadick, D.V.M., CPT, VC |
| Key Words: Adhesions, pelvic Adhesions, intraperitoneal | William Gregory, SPT5 Wendy Blomgren, SP5 |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: _____ | |
| Total Number of Subjects Enrolled to Date: _____ | |
| Date of Periodic Review _____ | Results _____ |

Objective(s): To study the incidence of pelvic and intraperitoneal adhesions when using synthetic sutures on peritoneal closure.

Technical Approach: Forty rabbits were used for this study. Animals were divided into four groups. One group was reperitonealized using braided polyglycolic suture, one was reperitonealized using chromic suture, one was repaired with PDS suture, and the final group had no sutures used on the peritoneum.

Progress: The study has been completed. However, final analysis of the data has not been completed.

Detail Summary Sheet

Date: 31 Oct 84 Proj No: A-6-84 Status: Ongoing
 Title: Development of a Primate Model of Carcinogen-Induced Transitional Cell Carcinoma.

| | |
|--|----------------------------|
| Start Date 5 Jun 84 | Est Comp Date: |
| Principal Investigator | Facility |
| Ian M. Thompson, M.D., CPT, MC | Brooke Army Medical Center |
| Dept/Svc | Associate Investigators: |
| Department of Surgery/Urology | |
| Key Words: | |
| Carcinoma, transitional cell | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): To develop a model of induced transitional cell carcinoma in the non-human primate.

Technical Approach: Transitional cell induction will be performed via oral carcinogen feeding in non-human primates. The implications of the study are tremendous with a ability to perfect a model which would allow controlled evaluation of surgical, chemotherapeutic, and radiation therapeutic modalities for the treatment of transitional cell carcinoma.

Progress: The study has not been started due to a lack of funds.

Detail Summary Sheet

| | | |
|---|-----------------|-------------------|
| Date: 31 Oct 84 | Proj No: A-7-84 | Status: Completed |
| Title: Chemoprophylaxis of Murine Transitional Cell Carcinoma Implantation. | | |

| | |
|---|---|
| Start Date 21 Aug 84 | Est Comp Date: |
| Principal Investigator Ian M. Thompson, M.D., CPT, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Surgery/Urology | Associate Investigators: William Gregory, SP5 Wendy Blomgren, SP5 |
| Key Words: Carcinoma, transitional cell | Edward J. Shumski, M.D., LTC, MC C. Ritchie Spence, M.D., COL, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: _____ | |
| Total Number of Subjects Enrolled to Date: _____ | |
| Date of Periodic Review _____ | Results _____ |
| Objective(s): To determine if intravesical chemotherapy can prevent bladder tumor implantation. | |

Technical Approach: Animals were randomly assigned to receive heparin prophylaxis before tumor instillation intravesically or to control irrigation.

Progress: No difference was noted between heparin pre-treated and control animals. However, a lesser number of animals in heparin pretreated control group were noted to develop tumors over the control irrigated animals. This effect will be studied further in the protocol A-3-84.

Detail Summary Sheet

Date: 31 Oct 84 Proj No: A-8-84 Status: Ongoing
Title: Intraarterial Infusion of Cisplatin in Combination with Hemoperfusion -
An Experimental Approach to Advanced Bladder Cancer.

| | |
|---|---|
| <u>Start Date</u> 21 Aug 84 | <u>Est Comp Date:</u> |
| <u>Principal Investigator</u> James B. Rounder, M.D., CPT, MC | <u>Facility</u> Brooke Army Medical Center |
| <u>Dept/Svc</u> Department of Surgery/Urology | <u>Associate Investigators:</u> Ian M. Thompson, M.D., CPT, MC Clayton L. Hadick, D.V.M., CPT, VC Wendy Blomgren, SP5 Frederic A. Lombardo, Ph.D., CPT, MSC C. Ritchie Spence, M.D., COL, MC |
| <u>Key Words:</u> Bladder cancer | |
| <u>Accumulative MEDCASE</u> | <u>Est Accumulative</u> |
| <u>Cost:</u> | <u>OMA Cost:</u> |
| <u>Number of Subjects Enrolled During Reporting Period:</u> _____ | |
| <u>Total Number of Subjects Enrolled to Date:</u> _____ | |
| <u>Date of Periodic Review</u> _____ | <u>Results</u> _____ |

Objective(s): To determine if intra-arterial infusion of Cisplatin (CDDP) in conjunction with direct hemoperfusion (DHP) will deliver a high concentration of anticancer drug to the bladder while reducing systemic levels of the drug.

Technical Approach: Yorkshire pigs are given varying dosages of Cisplatin via intraarterial infusion of the hypogastric system. This delivers high dose Cisplatin to the bladder and pelvis. The infusions are given in conjunction with direct hemoperfusion in an effort to reduce systemic levels of the drug.

Blood, urine, ultrafiltrates, and tissue samples are taken and analyzed for Cisplatin content. The animals are sacrificed at the end of the experiment.

Progress: AT this point, six animals have been evaluated. Cisplatin assays are underway, but no results are available at this time.

Detail Summary Sheet

Date: 31 Oct 84 Proj No: A-9-84 Status: Ongoing
Title: Development of an Animal Training Model of the Koch Continent Ileal Reservoir.

| | |
|---|--|
| <u>Start Date</u> 21 Aug 84 | <u>Est Comp Date:</u> |
| <u>Principal Investigator</u> Ian M. Thompson, M.D., CPT, MC | <u>Facility</u> Brooke Army Medical Center |
| <u>Dept/Svc</u> Department of Surgery/Urology | <u>Associate Investigators:</u> Clayton L. Hadick, D.V.M., CPT, VC Wendy Blomgren, SP5 James B. Rounder, M.D., CPT, MC Julius L. Teague, M.D., CPT, MC C. Ritchie Spence, M.D., COL, MC |
| <u>Key Words:</u> Ileal reservoir | |
| <u>Accumulative MEDCASE</u> | <u>Est Accumulative</u> |
| <u>Cost:</u> | <u>OMA Cost:</u> |
| <u>Number of Subjects Enrolled During Reporting Period:</u> | |
| <u>Total Number of Subjects Enrolled to Date:</u> | |
| <u>Date of Periodic Review</u> | <u>Results</u> |

Objective(s): To serve as a training protocol to teach the technique of creation of a continent ileal conduit to Urolgy residents at BAMC.

The development of a noncanine model for the long-term observation of anatomic results of the Koch ileal conduit.

Technical Approach: Thus far, six procine subjects have undergone a randomized trial of standard sutured versus surgically stapled Koch urinary ileal conduits. Animals have been sacrificed approximately one week postoperatively.

Progress: The initial two animals demonstrated pelvic abscesses, possibly due to ureteroileal leaks. However, subsequent animals did not demonstrate such extravasation and, despite intravenous fluid and antibiotic support, have survived without overt evidence of sepsis.

Detail Summary Sheet

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|-----------------------------------|------------------|-----------------|
| Date: 7 Nov 84 | Proj No: PVSG 12 | Status: Ongoing |
| Title: Hydroxyurea in Thrombosis. | | |

| | |
|---|--|
| Start Date FY 80 | Est Comp Date: |
| Principal Investigator Glenn M. Mills, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: |
| Key Words: Thrombosis | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: 6 | |
| Date of Periodic Review _____ Results _____ | |

Objective(s): To evaluate the efficacy of hydroxyurea in preventing and controlling the symptoms of thrombosis and bleeding with 1) the clinical entity primary thrombocytopenia, 2) those patients with myelofibrosis-myeloid metaplasia with elevated platelet counts, and 3) those patients with unclassified myeloproliferative disease with elevated platelet counts.

Technical Approach: In order to be eligible for entry on this study, the patient must meet the following criteria: 1) Absence of Philadelphia chromosome, 2) absence of an increased red cell mass, 3) bone marrow which shows marked megakaryocytic hyperplasia and abundant platelet clumps, 4) thrombosis not secondary to some identifiable cause, and 5) must not have had a pre-existing cancer, other than skin cancer.

Therapy will follow the schema outlined in the study protocol.

Progress: Six patients remain on the study and are doing well.

Detail Summary Sheet

| | | |
|---|--------------------|-----------------|
| Date: 1 Oct 84 | Proj No: SWOG 7804 | Status: Ongoing |
| Title: Adjuvant Chemotherapy with 5-Fluorouracil, Adriamycin, and Mitomycin-C (FAM) vs Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma. | | |

| | |
|---|---|
| Start Date FY 78 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Gastric adenocarcinoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 2 | |
| Date of Periodic Review 18 November 1983 Results Continue | |

Objective(s): To determine the efficacy of adjuvant chemotherapy with 5-FU, Adriamycin and Mitomycin-C (FAM) on the disease-free interval and survival of patients with TNM stage-groups IB, IC, II and III gastric adenocarcinoma compared to potentially curative surgery alone.

Technical Approach: Eligible patients must have localized lesions at least extending into the submucosa and involving any of the deeper layers with the maximum allowable penetration into but not through the serosa; localized lesions extending through serosa, with or without direct extension to contiguous structures; a lesion diffusely involving the wall of the stomach with or without metastases to immediately adjacent perigastric nodes or a localized lesion of any depth with metastases to perigastric nodes in the immediate vicinity; a localized or diffuse lesion with metastases to perigastric nodes distant from primary.

Therapy will follow the schema outlined in the study protocol.

Progress: One hundred fourteen patients are registered on this study (two from BAMC). Disease free survival between the surgery only and FAM arms are approaching statistical difference ($p = .08$) in favor of FAM. However, overall survival is no different for both arms with mean survival of 26 and 22 months for the control and FAM arms, respectively.

Detail Summary Sheet

Date: 1 Oct 84 Proj No: SWOG 7808 Status: Ongoing
Title: Combined Modality Treatment for Stages III and IV, Hodgkin's Disease -
MOPP #6.

| | |
|--|---------------------------------|
| <u>Start Date</u> FY 79 | <u>Est Comp Date:</u> |
| <u>Principal Investigator</u> | <u>Facility</u> |
| James F. Boyd, M.D., LTC, MC | Brooke Army Medical Center |
| <u>Dept/Svc</u> | <u>Associate Investigators:</u> |
| Department of Medicine/Oncology | Glenn M. Mills, M.D., MAJ, MC |
| <u>Key Words:</u> | |
| Hodgkin's Disease | |
| <u>Accumulative MEDCASE</u> | <u>Est Accumulative</u> |
| <u>Cost:</u> | <u>OMA Cost:</u> |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review 18 November 1983 | Results Continue |

Objective(s):

1. To attempt to increase the complete remission rate induced with MOP-BAP alone utilizing involved field radiotherapy in patients with Stages III and IV Hodgkin's disease achieving a PR at the end of 6 cycles of MOP-BAP.
2. To determine if immunotherapy maintenance with levamisole or consolidation with low dose involved field radiotherapy will produce significantly longer remission durations over a no further treatment group when CR has been induced with 6 cycles of MOP-BAP in Stages III and IV Hodgkin's disease.

Technical Approach: Eligible patients must have a histological diagnosis of Hodgkin's which must be classified by the Lukes and Butler system.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwise, there continues to be good response to radiation therapy.

Detail Summary Sheet

Date: 26 Mar 84 **Proj No:** SWOG 7823/4/5 **Status:** Closed
Title: ROAP-AdOAP in Acute Leukemia.

| | |
|---|---|
| Start Date FY 79 | Est Comp Date: |
| Principal Investigator J. Dean McCracken, M.D., COL, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: James F. Boyd, M.D., LTC, MC |
| Key Words: Acute Leukemia | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 13 | |
| Date of Periodic Review 18 November 1983 | Results Continue |

Objective(s): 1. To compare the efficacy of the 4-drug combination chemotherapy regimen, ROAP (Rubidazole, Vincristine, Arabinosol Cytosine, and Prednisone to AdOAP (the same combination using Adriamycin in place of Rubidazole) in adult acute leukemia, as determined by remission rate, remission duration and survival.

2. To determine the comparative toxicity of these regimens.
3. To determine whether late intensification therapy at 9 months after complete remission will improve long-term, disease-free survival.
4. To determine whether immunotherapy using levamisole for 6 months after 12 months of complete remission on chemotherapy improves disease-free survival.
5. To determine the effects of intrathecal Ara-C on the incidence of CNS leukemia.
6. To determine the reproducibility of the FAB/histologic classification and correlation to response to therapy in 200 consecutive cases of acute leukemia.
7. To study the effects of intensive supportive care in the management of acute leukemia.

Technical Approach: All patients over 15 years with a diagnosis of acute leukemia who have not received extensive therapy are eligible for this study. Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, the response rate remained at 60%. The study has been closed to new entries.

Detail Summary Sheet

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|---|--------------------|-----------------|
| Date: 1 Oct 84 | Proj No: SWOG 7827 | Status: Ongoing |
| Title: Combined Modality Therapy for Breast Carcinoma, Phase III. | | |

| | |
|--|---|
| Start Date FY 80 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Breast Carcinoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | 4 |
| Total Number of Subjects Enrolled to Date: | 36 |
| Date of Periodic Review 18 November 1983 | Results Continue |

Objective(s):

1. To compare the disease-free interval and recurrence rates in estrogen receptor positive (ER+) premenopausal patients with Stage II disease, using combination chemotherapy alone versus chemotherapy and oophorectomy.
2. To compare the disease-free interval and recurrence rates in estrogen receptor positive postmenopausal patients with Stage II disease, using combination chemotherapy plus tamoxifen versus tamoxifen alone versus combination chemotherapy alone.
3. To compare the disease-free interval and recurrence rates in all estrogen receptor negative (ER-) patients with Stage II disease using one versus two years of combination chemotherapy.
4. To compare the effect of these various adjunctive therapy programs upon the survival patterns of such patients.
5. To correlate the ER status with disease-free interval and survival.

Technical Approach: All patients must have had a radical or modified radical mastectomy with histologically proven breast cancer and with one or more pathologically proven axillary nodes. Primary neoplasm and clinically apparent axillary disease must be completely removed. Pretherapy studies must reveal no evidence of metastatic disease or involvement of the other breast. Therapy will follow the schema outlined in the study protocol.

Progress: The ER negative phase of the study has been completed. However, the ER positive components to this study need to accrue more patients. It is too early to comment on results at this time.

Detail Summary Sheet

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|--|---|----------------|
| Date: 1 Mar 84 | Proj No: SWOG 7841 | Status: Closed |
| Title: Phase I-II Comparison of FAM vs FAM + Vincristine vs Chlorozotocin in the Treatment of Advanced Gastric Adenocarcinoma. | | |
| Start Date FY 79 | Est Comp Date: | |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center | |
| Dept/Svc <u>Department of Medicine/Oncology</u> | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC | |
| Key Words: Gastric adenocarcinoma Chemotherapy | | |
| Accumulative MEDCASE | Est Accumulative | |
| Cost: | OMA Cost: | |
| Number of Subjects Enrolled During Reporting Period: 0 | | |
| Total Number of Subjects Enrolled to Date: 0 | | |
| Date of Periodic Review 18 November 1983 Results Continue | | |

Objective(s): 1) To determine whether or not vincristine increases the effectiveness (as determined by response rate and survival) of 5-FU plus mitomycin-C plus adriamycin (FAM) in the treatment of advanced, previously untreated gastric adenocarcinoma.

- 2) To determine the efficacy, as determined by response rate and survival, of chlorozotocin in the treatment of previously untreated gastric adenocarcinoma.
- 3) To determine by crossover, after relapse or failure on FAM, V-FAM or chlorozotocin, the effectiveness as determined by response rate and survival, of the alternate treatment in advanced gastric adenocarcinoma with prior therapy.
- 4) To determine the toxicities of such treatments.

Technical Approach: Patients must have histologically proven adenocarcinoma, Stage IV in extent, to be eligible for this study. They must not have received prior chemotherapy nor should they have received radiotherapy within four weeks of entry. Patients must have a minimum life expectancy of 6 weeks and a performance status of 0-3 in order to be eligible.

The protocol has been amended and arms being used are FAM vs DHAD.

Progress: This study has been closed to new entries.

Detail Summary Sheet

Date: 15 Mar 84 **Proj No:** SWOG 7916 **Status:** Completed
Title: Phase II Evaluation of Gallium Nitrate in Metastatic Urological
Malignancies: Testicular, Bladder, Prostate, and Kidney.

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|---|---|
| Start Date FY 80 | Est Comp Date: |
| Principal Investigator J. Dean McCracken, M.D., COL, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: James F. Boyd, M.D., LTC, MC |
| Key Words: Urological Malignancies | Glenn M. Mills, M.D., MAJ, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review 18 November 1983 | Results Continue |

Objective(s): To determine the efficacy of Gallium Nitrate, as determined by response rate, duration of response and survival, in patients with metastatic urological malignancies which includ: testicular, bladder, prostate, and kidney; who have failed on higher priority treatment protocols.

Technical Approach: All patients not eligible for higher priority SWOG studies with histologically proven, incurable, advanced, metastatic urological malignancies are eligible. Patients should not have had more than two previous types of combination or single agent chemotherapy trials. Patients must hve a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This protocol was closed with 17 patients with bladder cancer entered. There were two partial responses and one complete response with the responses having been seen in skin and a pelvic mass.

Detail Summary Sheet

Date: 15 Mar 84 Proj No: SWOG 7925 Status: Completed
 Title: Chemoimmunotherapy in Stages III and IV Ovarian Carcinoma: AC + BCG vs. AC + Cis-Platinum vs AC + Cis-Platinum + BCG.

| | |
|--|---|
| Start Date FY 80 | Est Comp Date: |
| Principal Investigator J. Dean McCracken, M.D., COL, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: James F. Boyd, M.D., LTC, MC Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Ovarian Carcinoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review 18 November 1983 | Results Continue |

Objective(s): 1) To compare the effectiveness of A-C + BCG vs A-C + Cis-Platinum for remission and induction and/or maintenance of disease-free status and prolongation of survival duration in patients with Stages III and IV ovarian carcinoma.

2) To compare the effectiveness of A-C + Cis-Platinum vs A-C + Cis-Platinum + BCG for remission induction and/or maintenance of disease-free status and prolongation of survival in patients with Stage III and IV ovarian carcinoma.

3) To compare the effectiveness of A-C + BCG vs A-C + Cis-Platinum + BCG for remission induction and/or maintenance of disease-free status and prolongation of survival duration in patients with Stages III and IV ovarian carcinoma.

4) To compare the toxicities of the A-C + BCG, A-C + Cis-Platinum and A-C + Cis-Platinum + BCG regimens.

Technical Approach: Only patients with epithelial type neoplasms will be eligible for this study. The patient must have histologically confirmed diagnosis of ovarian carcinoma.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, over 300 patients were registered on this study. Final analysis of the data indicates that there was evidence of a significantly prolonged survival in patients with measurable disease, Stages III and IV ovarian cancer treated with chemo-immunotherapy. This study was closed to new entries.

Detail Summary Sheet

Date: 15 Mar 84 Proj No: SWOG 7956 Status: Completed
 Title: Study of Postinfarction Nephrectomy and Medroxyprogesterone Acetate (Depo-Provera) in Metastatic Renal Cell Carcinoma.

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|--|---|
| Start Date FY 80 | Est Comp Date: |
| Principal Investigator J. Dean McCracken, M.D., COL, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: James F. Boyd, M.D., LTC, MC Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Renal Cell Carcinoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review 18 November 1983 | Results Continue |

Objective(s): 1) To determine the response rate and survival patterns in patients with disseminated renal cell carcinoma treated with postinfarction nephrectomy.

2) To determine the response rate and survival patterns of patients with disseminated renal cell carcinoma who relapse or do not respond to postinfarction nephrectomy when treated with Depo-Provera.

Technical Approach: Patients with measurable disseminated renal cell carcinoma who have not had removal of the primary cancer and in whom the metastatic disease is not resectable at the time of nephrectomy are eligible. Patients must have an expected survival of at least three months.

Therapy will follow the schema outlined in the study protocol.

Progress: Of the 66 patients entered on this study, one complete response was noted. The study was closed to new entries.

Detail Summary Sheet

Date: 1 Oct 84 Proj No: SWOG 7983 Status: Ongoing
 Title: Radiation Therapy in Combination with CCNU in Patients with Incompletely Resected Gliomas of the Brain, Grade I and II.

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|--|-----------------------------------|
| Start Date FY 80 | Est Comp Date: |
| Principal Investigator | Facility |
| James F. Boyd, M.D., LTC, MC | Brooke Army Medical Center |
| Dept/Svc | Associate Investigators: |
| Department of Medicine/Oncology | Glenn M. Mills, M.D., MAJ, MC |
| Key Words: | |
| Glioma | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | 0 |
| Total Number of Subjects Enrolled to Date: | 0 |
| Date of Periodic Review | 18 November 1983 Results Continue |

Objective(s): 1) To compare the survival of patients with incompletely resected Grade I and II gliomas treated with radiation alone vs radiation and CCNU.

2) To compare the effectiveness of radiotherapy vs radiation therapy plus CCNU for remission induction and duration of remission.

Technical Approach: Patients with histologically confirmed primary brain tumors of the following histologic types are eligible: Astrocytoma, Grade I and II with incomplete tumor resection. Patients who have had surgery with histologic diagnosis within the previous six weeks are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Evaluation of response rates continues to demonstrate an increase response rate in Treatment I with radiotherapy only, with 12 of 17 patients achieving a CR or PR. In Treatment II (radiation + drug), 12 of 25 patients have had a CR or PR with substantially less CR's noted. The p value for this difference is .066. Toxicity remains acceptable with no life-threatening or fatal toxicities.

Detail Summary Sheet

Date: 1 Oct 84 Proj No: SWOG 7984 Status: Ongoing
Title: Treatment of Chronic Stage CML with Pulse, Intermittent Busulfan Therapy
with or without Oral Vitamin-A, Phase III.

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| Start Date Nov 80 | Est Comp Date: |
| Principal Investigator vice McCracken Glenn M. Mills, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: James F. Boyd, M.D., LTC, MC |
| Key Words: Leukemia, Chronic Myelogenous | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: <u>0</u> | |
| Total Number of Subjects Enrolled to Date: <u>1</u> | |
| Date of Periodic Review 18 November 1983 | Results Continue |

Objective(s): To determine the efficacy of standard pulse, intermittent busulfan therapy plus oral Vitamin A in prolonging the chronic phase of CML, and hence in prolonging survival.

Technical Approach: All patients with newly diagnosed chronic stage CML will be eligible for entry onto this protocol. Patients who have had prior hydroxyurea and/or leukopheresis for less than seven days after initial diagnosis are likewise eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual on this study has increased since it was opened to CCOP's.

Detail Summary Sheet

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| Date: 1 Oct 84 | Proj No: SWOG 7990 | Status: Ongoing |
| Title: Testicular Cancer Intergroup Study. | | |

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| Start Date FY 80 Principal Investigator James F. Boyd, M.D., LTC, MC Dept/Svc Department of Medicine/Oncology Key Words: Testicular cancer | Est Comp Date: Facility Brooke Army Medical Center Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: <u>0</u> Total Number of Subjects Enrolled to Date: <u>0</u> Date of Periodic Review <u>18 November 1983</u> Results Continue | |

Objective(s): 1) To compare the disease-free survival and overall survival for surgery alone (with chemotherapy for relapsers) vs surgery plus early adjuvant chemotherapy in patients with resectable Stage II testicular cancer.

2) To register and follow patients with non-seminoma, non-choriocarcinoma stage I testicular cancer, to define prognostic variables which may predict recurrence in this stage group.

3) To define the difference in disease-free rates and patterns of recurrence based upon histologic subtypes and extent of disease on initial presentation.

4) To evaluate the role of marker substances such as human chorionic gonadotropin, alpha-fetoprotein, and lactic dehydrogenase in the early detection and management of recurrences in patients with stage I and stage II testicular carcinoma.

5) To evaluate the accuracy of lymphangiogram, CAT scans, and ultrasound studies for staging of retroperitoneal nodal involvement.

Technical Approach: Patients with histologically confirmed carcinoma of the testis, stage I or stage II, are eligible. Patients should enter the study between two and four weeks after lymphadenectomy.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available.

Detail Summary Sheet

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|--|--------------------|-----------------|
| Date: 1 Oct 84 | Proj No: SWOG 8001 | Status: Ongoing |
| Title: Evaluation of Two Maintenance Regimens in the Treatment of Acute Lymphoblastic Leukemia in Adults, Phase III. | | |

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| Start Date FY 80 Principal Investigator(vice McCracken) Glenn M. Mills, M.D., MAJ, MC Dept/Svc Department of Medicine/Oncology Key Words: Leukemia, Lymphoblastic | Est Comp Date: Facility Brooke Army Medical Center Associate Investigators: James F. Boyd, M.D., LTC, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: <u>2</u> | |
| Total Number of Subjects Enrolled to Date: <u>2</u> | |
| Date of Periodic Review <u>18 November 1983</u> Results <u>Continue</u> | |

Objective(s): 1) To evaluate the effectiveness, as determined by the complete remission rate of the L10 protocol using, Vincristine, Prednisone, and Adriamycin for induction, followed by intensive consolidation in the treatment of acute ALL.

2) To compare the effect on remission duration and survival of two maintenance regimens: the L10 "eradication" regimen vs cyclic therapy with POMP-COAP-OPAL.

3) To determine the reproducibility of the FAB histologic classification and correlation to response to therapy of ALL in adults.

Technical Approach: Patients are eligible with the diagnosis of acute lymphoblastic leukemia who satisfy the following criteria: a) Absolute infiltration of the marrow with >50% blasts (Absolute infiltration is defined as the total blast cell percentage (%) multiplied by the bone marrow cellularity percentage divided by 100); b) If the absolute infiltrate is 30-49%, evidence of progressive disease prior to entering the study will be required.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide data from 77 patients were evaluated. There were 54 complete remissions, 9 non-responders, and 14 early deaths. Ten of the early deaths occurred in patients greater than 50 years of age. The early deaths could not be attributed to overly aggressive therapy.

Detail Summary Sheet

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| Date: 1 Oct 84 | Proj No: SWOG 8006 | Status: Ongoing |
| Title: Postoperative Reductive Chemotherapy for Stage III or IV Operable Epidermoid Carcinoma of the Oral Cavity, Oropharynx, Hypopharynx, or Larynx, Phase III. | | |
| Start Date Nov 80 | Est Comp Date: | |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center | |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC | |
| Key Words: Epidermoid Carcinoma | | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | |
| Number of Subjects Enrolled During Reporting Period: 1 | | |
| Total Number of Subjects Enrolled to Date: 21 | | |
| Date of Periodic Review 18 November 1983 Results Continue | | |

Objective(s): To determine the length of remission, recurrence rates, survival rates, and pattern of recurrence for patients receiving therapy utilizing surgery and postoperative radiation vs combined therapy utilizing preoperative chemotherapy, surgery, and postoperative radiation therapy in operable Stage III or IV epidermoid carcinoma of the head and neck.

Technical Approach: Patients with operable lesions will be randomized between two therapeutic programs: Arm I - combined therapy including surgery and post-operative radiation therapy; or Arm 2 - combination chemotherapy followed by surgery and radiation therapy. Patients randomized to the chemotherapy limb will receive three courses of chemotherapy consisting of cis-platinum, methotrexate, vincristine, and bleomycin.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual continues to be good. No major toxicities have been reported.

Detail Summary Sheet

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|--|--------------------|-------------------|
| Date: 15 Mar 84 | Proj No: SWOG 8017 | Status: Completed |
| Title: 5-FU, Adriamycin, Streptozotocin, and Cyclophosphamide (FAC-S) in the Treatment of Metastatic Carcinoid Tumors, Phase II. | | |

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| Start Date Nov 80 | Est Comp Date: |
| Principal Investigator J. Dean McCracken, M.D., COL, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: James F. Boyd, M.D., LTC, MC Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Carcinoid | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review 18 November 1983 | Results Continue |

Objective(s): 1) To determine whether combination chemotherapy employing 5-FU, Cyclophosphamide, Adriamycin, and Streptozotocin is effective in the management of metastatic carcinoid.

2) To study the duration of survival of patients with metastatic carcinoid tumor treated with combination chemotherapy regimens.

3) To provide further information concerning the response and/or survival of patients with metastatic carcinoid originating in different sites and having different metastatic patterns.

Technical Approach: All patients must have biopsy-proven carcinoid tumor not amenable to further surgical therapy with no prior chemotherapy. A minimum life expectancy of 6 weeks and a performance status of 3 or better per Southwest Oncology Group criteria is necessary. All patients must have objectively measurable disease either as a measurable lesion or significant biochemical abnormality specific for their tumor.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, 73 patients were registered on this study. One complete response and 13 partial responses were observed in 53 patients eligible for evaluation. Median survival was 44 weeks.

Detail Summary Sheet

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| Date: 1 Oct 84 | Proj No: SWOG 8024 | Status: Ongoing |
| Title: Combined Modality Therapy for Disseminated Soft Tissue Sarcomas, Phase II. | | |

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| Start Date May 81 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Sarcoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review 18 November 1983 Results Continue | |

Objective(s): 1) To compare the effectiveness of bolus administration of Adriamycin and DTIC, to continuous infusion administration of Adriamycin and DTIC, in remission induction of patients with disseminated soft tissue sarcomas.

- 2) To compare the toxicities of these two drug schedules.
- 3) To determine the feasibility on a group-wide basis of surgical excision of accessible lesions in partially responding patients.
- 4) To compare the histology of the diagnostic lesion with the histology of tumor removed from the partial responder.

Technical Approach: Patients with a biopsy confirmed diagnosis of a soft tissue sarcoma with convincing clinical or biopsy-documented evidence of metastatic disease are eligible for this study. Patients must not have received prior chemotherapy with the agents used in this study. Patients must have a life expectancy of 10 weeks, and all patients must have lesion(s) which is measurable and can be followed for tumor response.

Progress: Groupwide, response rates remain low. Five patients showed complete response and 14 patients a partial response. Since reduction in the dose of DTIC in the infusion arm, there has been no significant difference in toxicity between the two arms.

Detail Summary Sheet

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|---|--------------------|-------------------|
| Date: 1 Mar 84 | Proj No: SWOG 8025 | Status: Completed |
| Title: Combination Chemotherapy for Chronic Lymphocytic Leukemia. | | |

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| Start Date 11 May 81 | Est Comp Date: |
| Principal Investigator J. Dean McCracken, M.D., COL, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: James F. Boyd, M.D., LTC, MC Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Leukemia, Chronic Lymphocytic | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | 0 |
| Total Number of Subjects Enrolled to Date: | 9 |
| Date of Periodic Review | 18 November 1983 Results Continue |

Objective(s): 1) To determine the response rate and duration of remission in patients with CLL treated with combination chemotherapy consisting of Prednisone, Vincristine, Cytosine Arabinoside, Cytoxan, and Adriamycin.

2) To correlate parameters obtained in the clinical, pathological, and immunological staging with response to treatment.

3) To determine the effect of stopping chemotherapy after patients have achieved a complete remission plus two consolidation courses, in order to define a cured or stabilized fraction of patients.

Technical Approach: All patients who fulfill the criteria for diagnosis of chronic lymphocytic leukemia according to the Rai Classification will be eligible for registration.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has been closed to new entries. The data are being analyzed.

Detail Summary Sheet

Date: 1 Mar 84 Proj No: SWOG 8030 Status: Completed
 Title: Evaluation of DHAD in Advanced Squamous Cell Carcinoma of the Head and Neck, Phase II.

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| Start Date 11 May 81 | Est Comp Date: |
| Principal Investigator J. Dean McCracken, M.D., COL, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: James F. Boyd, M.D., LTC, MC Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Head and Neck, Squamous Cell Carcinoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review _____ | Results _____ |

Objective(s): 1) To determine the response rate and remission duration in patients with advanced squamous cell carcinoma of the head and neck treated with DHAD used in a single dose every-three-week schedule.

2) To define further the qualitative and quantitative toxicities of DHAD.

Technical Approach: To be eligible for this study, patients must have a verified histologic diagnosis of squamous cell carcinoma of the head and neck region. All patients must have a life expectancy of at least three months.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, there are eleven evaluable patients on this study, and there have been no documented responses of adenoid cystic carcinoma to DHAD.

Detail Summary Sheet

Date: 15 Mar 84 **Proj No:** SWOG 8037 **Status:** Completed
Title: Combined Therapies for Squamous Cell Carcinoma of the Esophagus,
 Phase II.

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| Start Date 22 May 81 | Est Comp Date: |
| Principal Investigator J. Dean McCracken, M.D., COL, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: James F. Boyd, M.D., LTC, MC Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Squamous Cell Carcinoma, Esophagus | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 4 | |
| Total Number of Subjects Enrolled to Date: 6 | |
| Date of Periodic Review 18 November 1983 | Results Continue |

Objective(s): 1) To determine the feasibility and toxicity of combined radiotherapy and chemotherapy with 5-FU and Cis-Platinum followed by surgery in patients with epidermoid carcinoma of the middle or distal esophagus.

- 2) To determine the time to local or distant progression in patients treated by these three combined modalities.
- 3) To determine the survival of patients treated by these three combined modalities.
- 4) To determine the response rate by clinical and pathological staging at the time of surgery.

Technical Approach: Previously untreated patients with biopsy-proven squamous cell carcinoma of the middle or distal esophagus are eligible. Patients must be judged medically to be a surgical candidate for laparotomy and thoracotomy. Patients must have a life expectancy of 6 weeks or greater.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, 66 patients are evaluable. The complete response rate has been 25% and partial response rate 4.5%. Mean survival is now 51 weeks.

Detail Summary Sheet

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| Date: 8 Mar 84 | Proj No: SWOG 8038 | Status: Completed |
| Title: Vinblastine in Advanced Ovarian Cancer, Phase II. | | |

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| Start Date 11 May 81 | Est Comp Date: |
| Principal Investigator J. Dean McCracken, M.D., COL, MC | Facility Brooke Army Medical Center |
| Dept/Svc <u>Department of Medicine/Oncology</u> | Associate Investigators: James F. Boyd, M.D., LTC, MC Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Cancer, Ovarian | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review 18 November 1983 | Results Continue |

Objective(s): 1) To determine the response rate and remission duration with intravenous therapy using Velban as a continuous infusion in patients with advanced ovarian cancer.

2) To define further qualitative and quantitative toxicity of the continuous infusion of Velban.

Technical Approach: To be eligible, patients must have histologically confirmed, advanced, incurable ovarian cancer who are refractory to or ineligible for treatment on Southwest Oncology Group protocols of higher priority. Patients must have measurable disease and a life expectancy of six weeks or more.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, 10% of those enrolled on the study have responded (1 complete response and 2 partial responses).

Although the response rate to vinblastine was relatively low, it appears to have enough activity as a second line therapy to justify its inclusion in future multiagent trials of ovarian cancer in patients who have failed only one prior therapy.

Detail Summary Sheet

Date: 2 Oct 84 Proj No: SWOG 8040/44 Status: Ongoing
 Title: Evaluation of Combination Chemotherapy (FAM-S) vs a Phase II Drug in Pancreatic Adenocarcinoma, Phase II.

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| <u>Start Date</u> 22 May 81 | <u>Est Comp Date:</u> |
| <u>Principal Investigator</u> James F. Boyd, M.D., LTC, MC | <u>Facility</u> Brooke Army Medical Center |
| <u>Dept/Svc</u> Department of Medicine/Oncology | <u>Associate Investigators:</u> Glenn M. Mills, M.D., MAJ, MC |
| <u>Key Words:</u> Adenocarcinoma, Pancreas | |
| <u>Accumulative MEDCASE Cost:</u> | <u>Est Accumulative OMA Cost:</u> |
| <u>Number of Subjects Enrolled During Reporting Period:</u> 0 | |
| <u>Total Number of Subjects Enrolled to Date:</u> 0 | |
| <u>Date of Periodic Review</u> 18 November 1983 <u>Results</u> Continue | |

Objective(s): 1) To determine the response rate and survival in patients with advanced pancreatic adenocarcinoma treated with 5-FU, Adriamycin, Mitomycin-C, and Streptozotocin (FAM-S).

- 2) To determine further the toxicity of the FAM-S regimen.
- 3) To determine the activity of a Phase II drug in previously untreated patients with advanced adenocarcinoma of the pancreas by determination of response rate and duration of response and survival.
- 4) To determine further the toxicity of each Phase II agent.

Technical Approach: Patients with histologic confirmation of adenocarcinoma of the exocrine pancreas with distant metastases and/or those with localized disease not amenable to curative surgery or radiotherapy are eligible. All patients must have objectively measurable disease and a life expectancy of at least 10 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, 12 patients have been registered on AZQ with no responses observed. In the FAM-S arm there have been two complete responses and nine partial responses representing a response rate of 11%. One complete response and two partial responses have been observed in patients crossed over from Phase II agents. Survival in patients treated with MGBG before FAM was not significantly different; however, it was different in patients previously treated with DHAD, p=.001.

Detail Summary Sheet

Date: 8 Oct 84 **Proj No:** SWOG 8042 **Status:** Completed
Title: Evaluation of MGBG in Pancreatic Adenocarcinoma, Phase II.

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| Start Date 22 May 81 | Est Comp Date: |
| Principal Investigator J. Dean McCracken, M.D., COL, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: James F. Boyd, M.D., LTC, MC Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Adenocarcinoma, Pancreas | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review 18 November 1983 | Results Continue |

Objective(s): 1) To determine the response rate and its duration in patients with advanced adenocarcinoma of the pancreas treated with MGBG.
 2) To determine the qualitative and quantitative toxicities of MGBG when given on this schedule.

Technical Approach: See SWOG 8040/44.

Therapy will follow the schema outlined in the study protocol.

Progress: See SWOG 8040/44.

Detail Summary Sheet

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| Date: 18 Oct 84 | Proj No: SWOG 8044 | Status: Ongoing |
| Title: Evaluation of AZQ in Pancreatic Carcinoma, Phase II. | | |

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| Start Date 11 Feb 83 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Carcinoma, Pancreas | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: <u>3</u> | |
| Total Number of Subjects Enrolled to Date: <u>3</u> | |
| Date of Periodic Review _____ | Results _____ |

Objective(s): 1) To determine the antitumor activity of AZQ in pancreatic carcinoma.
 2) To further determine the nature and extent of AZQ in a Phase II study.

Technical Approach: See SWOG 8040/44.

Progress: This study remains open to accrue additional patients in order to adequately determine the activity of this drug in advanced pancreatic carcinoma.

Detail Summary Sheet

Date: 8 Oct 84 Proj No: SWOG 8049 Status: Ongoing
 Title: The Treatment of Resected, Poor Risk Prognosis Malignant Melanoma:
 Stage I - Surgical Excision vs Surgical Excision + Vitamin A, Phase III.

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| Start Date 9 Oct 81 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Malignant Melanoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review 18 November 1983 Results Continue | |

Objective(s): 1) To determine the efficacy of surgical excision or surgical excision plus vitamin A in preventing the recurrence of high-risk, Stage I malignant melanoma by determination of remission or disease-free interval.
 2) To determine the immunocompetence of patients with malignant melanoma and to determine the influence of vitamin A upon that immunocompetence.

Technical Approach: All patients with a histologically-confirmed diagnosis of high-risk Stage I malignant melanoma who have not been previously treated with chemotherapy, radiation therapy or immunotherapy are eligible. All patients must have had a wide local excision of the primary lesion.

Therapy will follow the schema outlined in the study protocol.

Progress: It is too early to report the results since this is a relapse and survival study.

Detail Summary Sheet

Date: 8 Oct 84 Proj No: SWOG 8092 Status: Ongoing
 Title: Human Tumor Stem Cell Assay Directed Chemotherapy for Ovarian Cancer.

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|---|---|
| Start Date 11 May 81 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Cancer, Ovarian Cell, Human Tumor Stem | |
| Accumulative MEDCASE Cost: | Est Accumulative CMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review | Results |

Objective(s): 1) To utilize the human tumor cloning assay to select single agent chemotherapy for patients with epithelial-type ovarian cancer, refractory to standard therapy.

2) To determine if the human tumor cloning system can be utilized to select individual patient's therapy in a cooperative group setting.

Technical Approach: Eligible patients must have a pathological diagnosis of epithelial-type ovarian cancer in pleural or peritoneal fluid. Patients should have measurable disease and a life expectancy of at least three months.

Progress: Fifty-two percent of the submitted specimens formed greater than 20 colonies per plate with a median number of colonies for a control plate of 51. The percent true positive rate for the assay with respect to the single agent correlations was 33% and for combination therapy was 66% with an overall predictive accuracy for response of 42%. The overall percent true negative for both single agent and combination agent therapy was 85%.

Detail Summary Sheet

Date: 8 Mar 84 Proj No: SWOG 8093 Status: Completed
 Title: Treatment of Metastatic Mesothelioma: A Comparison of Cyclophosphamide, DTIC and Adriamycin (CIA) vs Cyclophosphamide and Adriamycin (CA).

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| Start Date 9 Oct 81 | Est Comp Date: |
| Principal Investigator J. Dean McCracken, M.D., COL, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: James F. Boyd, M.D., LTC, MC |
| Key Words: Mesothelioma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review 18 November 1983 | Results Continue |

Objective(s): 1) To determine the effect of the drug combination Cyclophosphamide, DTIC, and Adriamycin vs Cyclophosphamide and Adriamycin (CA) on response rate, remission duration, and survival of patients with metastatic malignant mesothelioma in a prospective randomized Phase III clinical trial.

2) To determine the qualitative and quantitative toxicities of these two drug combinations.

3) To conduct an epidemiologic survey on all patients designed to identify important environmental factors which may place an individual at risk for the development of malignant mesothelioma.

Technical Approach: All patients must have histologically proven malignant mesothelioma of pleural or peritoneal origin with evidence of distant metastases or documented failure to previous radiation therapy. There must be an expected survival of at least 8 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, response rates have been very low in each treatment arm.

Detail Summary Sheet

Date: 8 Oct 84 Proj No: SWOG 8094 Status: Ongoing
 Title: Radiotherapy with and Without Chemotherapy for Malignant Mesothelioma
 Localized to One Hemithorax, Phase III.

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| Start Date 22 May 81 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Mesothelioma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | 0 |
| Total Number of Subjects Enrolled to Date: | 3 |
| Date of Periodic Review 18 November 1983 | Results Continue |

Objective(s): 1) To evaluate in a randomized prospective manner, the efficacy of Adriamycin in improving the disease-free interval in patients who will receive hemithoracic radiotherapy for Stage I pleural mesothelioma.

2) To further define prospectively the efficacy of radiotherapy to the involved hemithorax in patients with pleural mesothelioma.

Technical Approach: Eligible patients will have histologically confirmed malignant mesothelioma of the pleural cavity. Patients with measurable disease or evaluable disease as well as those in whom all gross disease has been resected will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, there have been two partial responses to radiotherapy out of 35 patients.

Detail Summary Sheet

Date: 1 Oct 84 Proj No: SWOG 8102 Status: Ongoing
 Title: Whole Brain Irradiation and Intrathecal Methotrexate in the Treatment of Solid Tumor Leptomeningeal Metastases.

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| Start Date 12 Feb 82 | Est Comp Date: Unknown |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., LTC, MC |
| Key Words: Leptomeningeal metastases | |
| Accumulative MEDCASE Cost: | Est Accumulative OIA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review 18 November 1983 | Results Continue |

Objective(s): To determine the response rate (CR + PR) of intrathecal methotrexate and whole brain irradiation in the control of solid tumor leptomeningeal metastases.

Technical Approach: All patients must have cerebrospinal fluid which is cytologically positive for malignant cells.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, 15 patients have been entered into this study. Thirteen are evaluable - 10 with breast cancer and 3 with non-breast cancers. None of the three non-breast cancer patients cleared their CSF of malignant cells. Of the 10 breast cancer patients, 5 have had a partial or complete response. In the responding patients, median survival has been 35 weeks.

Detail Summary Sheet

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| Date: 9 Oct 84 | Proj No: SWOG 8104 | Status: Ongoing |
| Title: Treatment of Advanced Seminoma (Stage cII(N ₄) + cIII) with Combined Chemotherapy and Radiation Therapy, Phase II. | | |

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| Start Date May 82 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Seminoma | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review 18 November 1984 Results Continue | |

Objective(s): To determine the response rate and survival patterns in patients with advanced seminoma (Stage cII (N₄) + cIII) treated with combined chemotherapy and radiation therapy.

Technical Approach: All patients with histologically proven, Stage cII (N₄) and cIII, advanced, pure or anaplastic testicular seminoma who have had no prior chemotherapy or radiation therapy are eligible. Patients must have no other evidence of malignant disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, 18 patients have been entered on the study. There have been five complete responses, three partial responses, and one patient with increasing disease.

Detail Summary Sheet

| | | |
|--|--------------------|-------------------|
| Date: 16 Mar 84 | Proj No: SWOG 8106 | Status: Completed |
| Title: Evaluation of AZQ (Carbamic Acid) in Central Nervous System Tumors, Phase II. | | |

| | |
|--|---|
| Start Date 12 Feb 82 | Est Comp Date: |
| Principal Investigator J. Dean McCracken, M.D., COL, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: James F. Boyd, M.D., LTC, MC Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Nervous System Tumors | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review 18 November 1983 | Results Continue |

Objective(s): 1) To determine the efficacy of AZQ given by intermittent bolus schedule in malignant gliomas by evaluation of response rate, duration, and survival.

2) To determine the qualitative and quantitative toxicities of AZQ given by this schedule in a Phase II setting.

Technical Approach: To be eligible, patients must have a histologically-confirmed diagnosis of astrocytoma, Grades III and IV; ependymoblastoma; medulloblastoma; or oligodendrogloma. Patients must have failed primary surgical and/or radiation therapies and not be eligible for higher priority protocols. All patients should have received adequate prior radiotherapy. Patients must have a life expectancy of six weeks or more.

Therapy will follow the schema outlined in the study protocol.

Progress: Forty-six patients are evaluable. Fifteen patients were treated on the good risk dose at 40 mg/M². No objective responses were observed. Two patients improved. Of 34 patients in the poor risk group receiving 30 mg/M², two patients responded with a partial remission.

Detail Summary Sheet

Date: 9 Oct 84 **Proj No:** SWOG 8107 **Status:** Ongoing
Title: Management of Disseminated Melanoma, Master Protocol, Phase II-III.

| | |
|---|--|
| Start Date 9 Jul 82 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Melanoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 1 | |
| Total Number of Subjects Enrolled to Date: 2 | |
| Date of Periodic Review 18 November 1983 Results Continue | |

Objective(s): To determine the effectiveness of cranial irradiation given electively in disseminated melanoma patients with lung and/or liver metastases to prevent or delay the clinical appearance of brain metastases..

Technical Approach: Patients should have histologic proof of melanoma and a negative radiographic study of the brain. Patients must have established disseminated melanoma with lung and/or liver metastases.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available.

Detail Summary Sheet

| | | |
|---|--------------------|-------------------|
| Date: 16 Mar 84 | Proj No: SWOG 8108 | Status: Completed |
| Title: Evaluation of Bisantrene Hydrochloride in Refractory Multiple Myeloma, Phase II. | | |

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|----------------------------------|------------------------------|
| Start Date 14 May 82 | Est Comp Date: |
| Principal Investigator | Facility |
| J. Dean McCracken, M.D., COL, MC | Brooke Army Medical Center |
| Dept/Svc | Associate Investigators: |
| Department of Medicine/Oncology | James F. Boyd, M.D., LTC, MC |
| Key Words: Multiple Myeloma | |

| | |
|---|------------------|
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review 18 November 1983 Results Continue | |

Objective(s): 1) To determine the response rate and response duration of refractory multiple myeloma treated with bisantrene hydrochloride used in a single dose, every three-week schedule.

2) To define the qualitative and quantitative toxicities of bisantrene administered in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of multiple myeloma. Bisantrene hydrochloride is intended for therapy of patients with multiple myeloma who have had prior exposure to, and progression of disease on, protocols of higher priority.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has been closed to new entries. There have been no partial responses with bisantrene although several patients did show minor improvement.

Detail Summary Sheet

| | | |
|--|---|-----------------|
| Date: 9 Oct 84 | Proj No: SWOG 8110 | Status: Ongoing |
| Title: Treatment of Advanced Germ Cell Neoplasms of the Testis: A Comparison of Remission Induction with Vinblastine, Bleomycin and Cis-Platinum vs Vinblastine, Cis-Platinum and VP-16; Surgical Removal of All Residual Tumor... vs. Observation | | |
| Start Date 11 Jun 82 | Est Comp Date: | |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center | |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC | |
| Key Words: Germ Cell Neoplasms Testis | | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | |
| Number of Subjects Enrolled During Reporting Period: 3 | | |
| Total Number of Subjects Enrolled to Date: 6 | | |
| Date of Periodic Review 18 November 1983 Results Continue | | |

Objective(s): 1) To compare in a randomized fashion the effectiveness of the drug combination Vinblastine, Cis-Platinum, and VP-16 vs Vinblastine, Bleomycin and Cis-Platinum in the remission induction of patients with disseminated germ cell neoplasms of testicular origin.

2) To determine the role of six months maintenance chemotherapy vs observation for those patients who achieve a complete response during induction, or have a totally resected mature teratoma, in terms of relapse-free survival and overall survival.

3) To determine the role of six months maintenance chemotherapy vs observation for those patients with residual carcinoma having no evidence of disease following surgery, in terms of relapse-free survival and overall survival.

4) To document the nature and extent of the hematologic and non-hematologic side effects of the treatment modalities.

Technical Approach: Patients should have a histologically confirmed diagnosis of disseminated germ cell neoplasms of testicular origin. All patients with bulky abdominal disease (Stage cII(N₄) or Stage cIII) will be eligible for the study. Patients should have an expected survival of at least eight weeks.

Progress: Groupwide, minimal disease patients achieved complete response rates better than those with maximal disease.

Detail Summary Sheet

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|--|--------------------|-----------------|
| Date: 9 Oct 84 | Proj No: SWOG 8111 | Status: Ongoing |
| Title: The Treatment of Dissected, Poor Prognosis Malignant Melanoma: Stage II - Surgical Excision vs Surgical Excision + Vitamin A vs Surgical Excision + Actinomycin-D and DTIC. | | |

| | |
|---|---|
| Start Date 13 May 83 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Malignant Melanoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review 18 November 1983 Results Continue | |

Objective(s): To determine the efficacy of surgical excision plus vitamin A, and surgical excision plus combination chemotherapy (Actinomycin-D and DTIC) in preventing the recurrence of Stage II malignant melanoma by the determination of remission duration or disease-free interval.

Technical Approach: All patients must have a histologically confirmed diagnosis of lymph node melanoma and complete and adequate surgical excision of all residual disease. Patients with completely resected mucosal melanoma or first recurrence will be eligible, but will be stratified separately at the time of registration. All patients must be randomized and treatment begun within six weeks of the lymph node resection.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, patient accrual on this study has been extremely slow. No reportable data are available.

Detail Summary Sheet

Date: 16 Mar 84 **Proj No:** SWOG 8116 **Status:** Completed
Title: Evaluation of Bisantrene Hydrochloride in Refractory Lymphoma, Phase II.

| | |
|---|---|
| Start Date 9 Apr 82 | Est Comp Date: |
| Principal Investigator J. Dean McCracken, M.D., COL, MC | Facility Brooke Army Medical Center |
| Dept/Svc <u>Department of Medicine/Oncology</u> | Associate Investigators: James F. Boyd, M.D., LTC, MC |
| Key Words: Lymphoma | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review 18 November 1984 | Results Continue |

Objective(s): 1) To determine the response rate and response duration of malignant lymphoma treated with bisantrene hydrochloride used in a single dose, every three-week schedule.

2) To define the qualitative and quantitative toxicities of bisantrene hydrochloride administered in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of malignant lymphoma. Bisantrene is intended for therapy of patients with refractory lymphomas who have had prior exposure to, and progression of disease on, protocols of higher priority. Patients must have evaluable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, by tumor type, there have been 0/9 responses in Hodgkin's disease, 1/4 in nodular lymphoma and 2/14 in diffuse lymphoma. This drug appears to have limited activity in heavily pretreated patients with lymphoma.

Detail Summary Sheet

Date: 9 Oct 84

Proj No: SWOG 8118

Status: Ongoing

Title: Evaluation of Bisantrene Hydrochloride in Refractory Malignant Melanoma, Phase II.

| | |
|---|--|
| Start Date 9 Apr 82 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Malignant Melanoma | |

| | |
|--|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | 0 |
| Total Number of Subjects Enrolled to Date: | 1 |

Date of Periodic Review 18 November 1984 **Results** Continue

Objective(s): 1) To determine the response rate and response duration of malignant melanoma treated with bisantrene hydrochloride used in a single dose, every three-week schedule.

2) To define the qualitative and quantitative toxicities of bisantrene administered in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of melanoma. Bisantrene is intended for therapy of patients who have had prior exposure to, and progression of disease on, protocols of higher priority. Patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: No responses have been noted. However, it is too early to state whether the drug appears to be effective in this disease.

Detail Summary Sheet

Date: 9 Oct 84 Proj No: SWOG 8119 Status: Ongoing
 Title: Evaluation of Bisantrene Hydrochloride in Hepatoma.

| | |
|--|---|
| Start Date 9 Apr 82 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Hepatoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 1 | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review 18 November 1984 | Results Continue |

Objective(s): 1) To determine the response rate and response duration of hepatomas treated with bisantrene hydrochloride used in a single dose, every three-week schedule.

2) To define the qualitative and quantitative toxicities of bisantrene administration in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of hepatoma. Bisantrene is intended as therapy of patients with extensive disease or those patients not eligible or relapsing on protocols of higher priority. Patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: No responses have been noted in six evaluable patients. The study will remain open to accrue 14 evaluable patients.

Detail Summary Sheet

| | | |
|---|--------------------|-------------------|
| Date: 16 Mar 84 | Proj No: SWOG 8120 | Status: Completed |
| Title: Evaluation of Bisantrene Hydrochloride in Gastric Carcinoma. | | |

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|--|--|
| Start Date 9 Apr 82 | Est Comp Date: |
| Principal Investigator J. Dean McCracken, M.D., COL, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: James F. Boyd, M.D., LTC, MC |
| Key Words: Gastric Carcinoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 1 | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review 18 November 1984 Results Continue | |

Objective(s): 1) To determine the response rate, response duration, and duration of survival of gastric carcinoma patients treated with bisantrene hydrochloride used in a single dose, every three-week schedule.

2) To define the qualitative and quantitative toxicities of bisantrene hydrochloride administered in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of adenocarcinoma of the stomach with gross unresectable residual disease. Bisantrene is intended for therapy of patients with gastric carcinoma not eligible for protocols of higher priority and patients relapsing on protocols of higher priority. Patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, 27 patients were entered on study, with 21 fully evaluable, and 4 partially evaluable. One partial response was observed for three months. Bisantrene appears to have only modest effectiveness in gastric carcinoma.

Detail Summary Sheet

Date: 9 Oct 84 Proj No: SWOG 8122 Status: Ongoing
 Title: Combined Modality Treatment of Extensive Small Cell Lung Cancer, Phase III.

| | |
|--|---|
| Start Date 14 May 82 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Small Cell Lung Cancer | |
| Accumulative MEDCASE Cost: | Est Accumulative CMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | 5 |
| Total Number of Subjects Enrolled to Date: | 10 |
| Date of Periodic Review 18 November 1984 | Results Continue |

Objective(s): 1) To compare the response rate and duration of a new induction program (multiple alkylating agents plus Vincristine), with emphasis on complete response, to the combination of Vincristine, Adriamycin, and Cyclophosphamide in the treatment of extensive small cell lung cancer.

2) To examine the effect of radiation consolidation on relapse in the chest and liver in patients without widespread skeletal disease.

3) To assess qualitative and quantitative toxicity of this combined modality approach.

4) To perform a prospective analysis, by electron microscopy, of the available material for clinicopathologic correlation.

5) To evaluate the effectiveness of a more aggressive radiation therapy approach to clinically evident brain metastases.

6) To evaluate the impact of chest radiation therapy following relapse as to the duration of response and survival.

7) To improve survival and the quality of life in patients with extensive small cell lung cancer.

Technical Approach: All patients with extensive small cell carcinoma of the lung are eligible for entry onto this study. Patients must not have had prior treatment with chemotherapy or radiation therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 9 Oct 84 **Proj No:** SWOG 8124/5/6 **Status:** Ongoing

Title: Treatment of Acute Non-Lymphocytic Leukemia with Conventional Induction, Consolidation Chemotherapy: Maintenance with Chemotherapy vs Bone Marrow Transplantation Following Total Body Irradiation, Phase III.

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|---|---------------------------------|-----------------------------------|-------------------------------|
| Start Date | 12 Nov 82 | Est Comp Date: | Unknown |
| Principal Investigator | James F. Boyd, M.D., LTC, MC | Facility | Brooke Army Medical Center |
| Dept/Svc | Department of Medicine/Oncology | Associate Investigators: | Glenn M. Mills, M.D., MAJ, MC |
| Key Words: | Acute non-lymphocytic leukemia | | |
| Accumulative MEDCASE Cost: | | Est Accumulative OMA Cost: | |
| Number of Subjects Enrolled During Reporting Period: | 0 | | |
| Total Number of Subjects Enrolled to Date: | 0 | | |
| Date of Periodic Review | | Results | |

Objective(s): To determine the complete remission-rate with intensive induction chemotherapy in patients with acute non-lymphocytic leukemia, focusing attention on those patients over 50 years of age.

To compare duration of remission and survival of patients receiving maintenance with or without intensification chemotherapy versus those patients receiving an HLA identical sibling bone marrow transplant while in first remission.

To determine the comparative toxicity of these regimens.

To compare the continuous maintenance therapy and late intensification with late intensification alone.

Evaluate the prognostic significance of any chromosome abnormalities in leukemic cell lines.

Technical Approach: All patients with a diagnosis of acute non-lymphocytic leukemia who have not received prior therapy and who do not have initial CNS leukemia will be eligible for this study. There are no age restrictions; however, patients over the age of 50 will not be considered for bone marrow transplantation.

PROGRESS: Sixty-one percent of the patients have obtained a complete remission but the response rate is quite age-dependent. Eighty percent of the patients achieving a CR were less than age 50, 46% of those were 40-64 years old and 33% were over age 64. On the bone marrow transplant arm, 20 patients have been transplanted, 19 in first remission and 1 in early relapse. Twelve of these patients are alive.

For patients undergoing marrow transplant in first remission, those less than age 20 have long-term survival rate of about 70%, ages 20-29 have 40-50%, and age 30-50 have 20-30%.

Detail Summary Sheet

Date: 22 May 84 **Proj No:** SWOG 8161 **Status:** Completed
Title: Evaluation of Bisantrene Hydrochloride in Adult Acute Leukemia, Phase II, Pilot.

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|--|---|
| Start Date 9 Apr 82 | Est Comp Date: |
| Principal Investigator Glenn M. Mills, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: James F. Boyd, M.D., LTC, MC |
| Key Words: Acute leukemia | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | 2 |
| Total Number of Subjects Enrolled to Date: | 3 |
| Date of Periodic Review | Results |

Objective(s): 1) To determine the response rate and response duration of adult acute leukemia treated with bisantrene hydrochloride.
 2) To define the qualitative and quantitative toxicities of bisantrene when administered daily for five days every three weeks.

Technical Approach: All patients must have pathologically verified histologic diagnosis of adult acute leukemia. The diagnosis of adult acute leukemia will be made by bone marrow smear and an absolute infiltrate of 50% leukemic cells or greater. Bisantrene is intended for therapy of patients with adult acute leukemia in relapse who have had prior exposure to, and progression of disease on protocols of higher priority. Patients must not be receiving concomitant chemotherapy while on this protocol.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, 28 patients have been entered on study. There were 16 fully evaluable patients with one CR and one PR among five patients with ALL who received the drug, and one CR and one PR among eleven patients with AML who received the drug. The study was closed.

Detail Summary Sheet

Date: 16 Oct 84 **Proj No:** SWOG 8200 **Status:** Ongoing
Title: Evaluation of Vinblastine by Continuous Infusion for Advanced, Recurrent Endometrial Carcinoma, Phase II.

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|---|--|
| Start Date 14 May 82 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Endometrial Carcinoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: <u>0</u> | |
| Total Number of Subjects Enrolled to Date: <u>0</u> | |
| Date of Periodic Review | Results |

Objective(s): To evaluate the efficacy of a five day vinblastine infusion with respect to remission induction, remission duration, and survival duration in patients with advanced, recurrent, or Stages III and IV endometrial carcinoma refractory to prior chemotherapy.

Technical Approach: Patients with pathologically proven adenocarcinoma of adenosquamous carcinoma of the endometrium who have recurrent disease, or Stage III or IV disease no longer treatable with radiation therapy or surgery, are eligible. Patients must not have received prior chemotherapy with vinca alkaloids. Patients may have had previous chemotherapy of other types. Patients must have clinically measurable disease either by radiologic techniques or physical examination.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available.

Detail Summary Sheet

Date: 16 Oct 84 **Proj No:** SWOG 8203/04 **Status:** Ongoing

Title: Randomized Comparison of Adriamycin, Mitoxantrone and Bisantrene in Patients with Metastatic Breast Cancer not Previously Exposed to Intercalating Chemotherapy, Phase III.

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|---|--|-----------------------------------|-------------------------------|
| Start Date | 10 Dec 82 | Est Comp Date: | Unknown |
| Principal Investigator | James F. Boyd, M.D., LTC, MC | Facility | Brooke Army Medical Center |
| Dept/Svc | Department of Medicine/Oncology | Associate Investigators: | Glenn M. Mills, M.D., MAJ, MC |
| Key Words: | Metastatic Breast Cancer Intercalating Chemotherapy | | |
| Accumulative MEDCASE Cost: | | Est Accumulative OMA Cost: | |
| Number of Subjects Enrolled During Reporting Period: | 5 | | |
| Total Number of Subjects Enrolled to Date: | 8 | | |
| Date of Periodic Review | | Results | |

Objective(s):

- 1) To determine the comparative response rate, duration of response, and survival of equimyelosuppressive doses of Adriamycin, Mitoxantrone, and Bisantrene as single agents in breast cancer patients, not previously exposed to an intercalating agent, using a single dose, every-three-week regimen.
- 2) To determine the salvage response rate of Adriamycin, Mitoxantrone, or Bisantrene in breast cancer patients failing one of these three agents.
- 3) To assess the cardiotoxicity of Adriamycin, Mitoxantrone, and Bisantrene as determined by history, physical examination, and measurement of the left ventricular ejection fraction.
- 4) To compare the relative noncardiac toxicities of the three agents.

Technical Approach: Patients must have a pathologically verified diagnosis of breast cancer in order to be eligible for this study. Patients must have objectively measurable or evaluable lesion(s) excluding CNS metastases. Patients must not have been previously treated with Adriamycin, Mitoxantrone, or Bisantrene, but must have had only one prior chemotherapy regimen as adjuvant therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: Responses have been seen in each of the three arms, and responses have been seen in crossover. It is too early to report on any comparative results.

Detail Summary Sheet

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|--|--------------------|-------------------|
| Date: 22 May 84 | Proj No: SWOG 8207 | Status: Completed |
| Title: AZQ in Advanced Renal Cell Carcinoma. | | |

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|--|--|
| Start Date 10 Sep 82 | Est Comp Date: |
| Principal Investigator J. Dean McCracken, M.D., COL, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: James F. Boyd, M.D., LTC, MC |
| Key Words: Renal Cell Carcinoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review | Results |

Objective(s): 1) To determine the response rate and duration of response in patients with advanced renal cell carcinoma treated with AZQ used in a single dose, every three-week schedule.

2) To define the qualitative and quantitative toxicities of AZQ administered in a Phase II study.

Technical Approach: All patients with a diagnosis of histologically proven, advanced renal cell carcinoma not eligible for higher priority Southwest Oncology Group protocols are eligible. Patients must have clearly measurable disease and a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: The protocol was amended to a lower dose range; however, toxicity remained high and there was only one partial response.

Detail Summary Sheet

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|---|--------------------|-----------------|
| Date: 16 Oct 84 | Proj No: SWOG 8208 | Status: Ongoing |
| Title: Trial of Chlorozotocin and 5-FU in Metastatic Islet Cell Carcinoma, Phase II | | |

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|--|---|
| Start Date 11 Mar 83 | Est Comp Date: Unknown |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Islet cell carcinoma | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review | Results |

Objective(s): 1) To study the response of functioning and non-functioning islet cell carcinoma to chlorozotocin (CTZ) and 5-fluorouracil (5-FU).

2) To determine the toxicity of 5-FU and CTZ when given in combination.

Technical Approach: To be eligible for this study, all patients must have biopsy-proven islet cell carcinoma not amenable to further surgical therapy; and a minimum life expectancy of greater than six weeks. All patients must have objectively measurable disease, or a significant biochemical abnormality secondary to endocrine hyperfunction specific for their islet cell tumors.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, nine patients have been entered on this study. The data is too preliminary to report at this time. No severe or unacceptable toxicities have been observed to date.

Detail Summary Sheet

| | | |
|---|--------------------|-------------------|
| Date: 4 Jun 84 | Proj No: SWOG 8209 | Status: Completed |
| Title: A Study of AZQ in Soft Tissue and Bone Sarcomas. | | |

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|--|--|
| Start Date 10 Dec 82 | Est Comp Date: |
| Principal Investigator J. Dean McCracken, M.D., COL, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: James F. Boyd, M.D., LTC, MC |
| Key Words: Soft tissue sarcoma Bone sarcoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review Results | |

Objective(s): 1) To determine the antitumor activity of Aziridinylbenzo-quinone (AZQ) in soft tissue and bony sarcomas by determination of the response rate and the remission duration.

2) To further determine the nature and extent of AZQ toxicity in a Phase II study.

Technical Approach: Eligible patients must have histologically proven advanced soft tissue bony sarcomas, no amenable to surgery or treatment with Southwest Oncology Group Studies of higher priority. Patients must have a life expectancy of six weeks or more and a performance status of 2 or better. They must not have had prior chemotherapy or radiation therapy within three weeks and recovery must have occurred from the acute toxicities of these treatments.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, 51 patients were entered on the study with 35 in the good risk category and 16 in the poor risk category. In the good risk category, 14% had life-threatening toxicity and 79% had life-threatening toxicity in the poor risk group. No responses were noted.

Detail Summary Sheet

Date: 4 Jun 84 **Proj No:** SWOG 8210 **Status:** Terminated

Title: A Comparison of Aggressive Radiotherapy Plus Chemotherapy Versus Aggressive Chemotherapy in the Treatment of Limited Carcinoma of the Pancreas.

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|---|--|
| Start Date 12 Nov 82 | Est Comp Date: |
| Principal Investigator J. Dean McCracken, M.D., COL, MC | Facility Brooke Army Medical Center |
| Dept/Svc <u>Department of Medicine/Oncology</u> | Associate Investigators: LTC James F. Boyd |
| Key Words: Carcinoma of pancreas | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 3 | |
| Date of Periodic Review | Results |

Objective(s): 1) To determine whether aggressive therapy with combination radiotherapy/chemotherapy or chemotherapy alone yields superior survival in patients with incurable localized pancreatic cancer.

2) To compare the toxicities of the two programs.

Technical Approach: Surgical exploration is required to establish truly unresectable localized disease. Patients must have a histological confirmation of adenocarcinoma of the exocrine pancreas. Patients must have a life expectancy of at least 10 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This study accrued only 24 patients since activation. No responses were observed in either arm.

Detail Summary Sheet

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|--------|---|----------|-----------|---------|---------|
| Date: | 12 Nov 84 | Proj No: | SWOG 8211 | Status: | Ongoing |
| Title: | Evaluation of Cis-Diamminedichloroplatinum in Disseminated Gastric Adenocarcinoma, Phase II | | | | |

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|---|-------------------------------|----------------|---------|
| Start Date | 8 Oct 82 | Est Comp Date: | Unknown |
| Principal Investigator | Facility | | |
| James F. Boyd, M.D., LTC, MC | Brooke Army Medical Center | | |
| Dept/Svc | Associate Investigators: | | |
| Department of Medicine/Oncology | Glenn M. Mills, M.D., MAJ, MC | | |
| Key Words: | | | |
| Gastric adenocarcinoma | | | |
| Accumulative MEDCASE | Est Accumulative | | |
| Cost: | OMA Cost: | | |
| Number of Subjects Enrolled During Reporting Period: <u>0</u> | | | |
| Total Number of Subjects Enrolled to Date: <u>1</u> | | | |
| Date of Periodic Review | Results | | |

Objective(s): 1) To test the response-rate of cis-diamminedichloroplatinum (DDP) in patients with disseminated and measurable adenocarcinoma of the stomach who are previously untreated.

2) To test the response-rate of cis-diamminedichloroplatinum in patients with disseminated adenocarcinoma of the stomach who are previously treated with 5-fluorouracil, Adriamycin, and Mitomycin-C (5-FAM) chemotherapy.

Technical Approach: Eligible patients must have a histologically proven gastric adenocarcinoma and be considered inoperable for cure at the time of entry on the study. Patients must have a life expectancy of six weeks or longer.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, 25 patients have been registered on this study. No responses were recorded.

Detail Summary Sheet

Date: 4 Jun 84 Proj No: SWOG 8214 Status: Completed
 Title: Evaluation of Bisantrene Hydrochloride in Advanced Sarcoma, Phase II

| | |
|--|--|
| Start Date 12 Nov 82 | Est Comp Date: |
| Principal Investigator J. Dean McCracken, M.D., COL, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: James F. Boyd, M.D., LTC, MC |
| Key Words: Sarcoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review _____ Results _____ | |

Objective(s): 1) To determine the response rate and response duration of advanced sarcoma treated with bisantrene hydrochloride used in a single dose, every-three-week schedule.

2) To define the qualitative and quantitative toxicities of bisantrene administered in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of sarcoma. Every effort should be made to include patients who have not been treated with more than one prior chemotherapy regimen and also to admit those patients with no prior chemotherapy who do not otherwise qualify for higher priority Southwest Oncolong Group protocols.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, 22 patients were entered on this protocol. Sixteen were in the good risk category and 6 in the poor risk category. No responses were seen in the evaluable patients.

Detail Summary Sheet

| | | |
|--|--------------------|-----------------|
| Date: 12 Nov 84 | Proj No: SWOG 8215 | Status: Ongoing |
| Title: Comparison of Combination Chemotherapy with VP-16 and Cis-Platinum vs BCNU, Thiotapec, Vincristine and Cyclophosphamide in Patients with Small Cell Carcinoma of the Lung Who Have Failed or Relapsed Primary Chemotherapy, Phase 3 | | |

| | |
|---|--|
| Start Date 8 Jul 83 | Est Comp Date: |
| Principal Investigator <u>James F. Boyd, M.D., LTC, MC</u> | Facility <u>Brooke Army Medical Center</u> |
| Dept/Svc <u>Department of Medicine/Oncology</u> | Associate Investigators: <u>Glenn M. Mills, M.D., MAJ, MC</u> |
| Key Words: <u>Small cell lung carcinoma</u> | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: <u>0</u> | |
| Total Number of Subjects Enrolled to Date: <u>0</u> | |
| Date of Periodic Review | Results |

Objective(s): 1) To confirm the efficacy of combination VP-16-213 (VP-16) and Cis-diamminedichloroplatinum (Cis-Platinum) in the treatment of patients with small cell carcinoma of the lung who have failed or relapsed on first-line treatment protocols.

2) Through a randomized trial, to compare the remission rate, duration of remission, and toxicity between the combination of VP-16 plus Cis-Platinum and the combination of bis-chloroethylnitrosourea (BCNU), triethylenethiophosphoramide (Thiotapec), Vincristine (Oncovin) and Cyclophosphamide (Cytoxan) in the same group of patients.

Technical Approach: For inclusion in the study, patients must have a histologically proven diagnosis of small cell carcinoma of the lung and documented relapse or progression following prior therapy. Patients must have had prior chemotherapy. All patients who have relapsed on first-line Southwest Oncology Group protocols for either extensive disease or limited disease, or who have had prior chemotherapy with other induction studies are eligible. Patients may have had prior treatment with any of the agents used in this study, but not with either of the two combinations to be employed. All patients must have a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Thus far, only 1/11 responders have been seen on the BTOC arm of this study, and 1/17 on the cis-platinum plus VP-16 arm. The study remains open until a replacement arm utilizing a Phase II agent can be developed.

Detail Summary Sheet

Date: 12 Nov 84 Proj No: SWOG 8217 Status: Ongoing
 Title: Evaluation of Spirogermanium in Adenocarcinoma of the Prostate, Phase II

| | |
|--|---|
| Start Date 8 Oct 82 | Est Comp Date: Unknown |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Adenocarcinoma of prostate | |
| Accumulative MEDCASE Cost: | Est Accumulative CMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review | Results |

Objective(s): 1) To determine the response rate and remission duration of adenocarcinoma of the prostate when treated with Spirogermanium, used as a 60 minute infusion in a three times weekly schedule.

2) To define the qualitative and quantitative toxicities of Spirogermanium administered in a Phase II study.

Technical Approach: All patients must have a histologically proven diagnosis of adenocarcinoma of the prostate. They must have evaluable or measurable disease and a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Eighteen patients are evaluable. There have been two partial responses. The responses were seen in one patient who had improved bone scan and normalization of acid phosphatase and the other of the prostate gland.

Detail Summary Sheet

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|---|------------------|-----------------|------------------|----------------|----------------|
| Date: | 12 Nov 84 | Proj No: | SWOG 8219 | Status: | Ongoing |
| Title: Evaluation of Combined or Sequential Chemo-Endocrine Therapy in Treatment of Advanced Adenocarcinoma of the Prostate, Phase III | | | | | |

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|--|------------------|-----------------------------------|--|
| Start Date | 12 Nov 82 | Est Comp Date: | |
| Principal Investigator | | Facility | |
| James F. Boyd, M.D., LTC, MC | | Brooke Army Medical Center | |
| Dept/Svc | | Associate Investigators: | |
| Department of Medicine/Oncology | | Glenn M. Mills, M.D., MAJ, MC | |
| Key Words: | | | |
| Adenocarcinoma of prostate | | | |
| Accumulative MEDCASE Cost: | | Est Accumulative OMA Cost: | |
| Number of Subjects Enrolled During Reporting Period: <u>0</u> | | | |
| Total Number of Subjects Enrolled to Date: <u>5</u> | | | |
| Date of Periodic Review | | Results | |

Objective(s): To compare the efficacy of the sequential use of endocrine therapy followed at the time of progression by cytotoxic chemotherapy (Adriamycin and cyclophosphamide) versus the combination of endocrine therapy and chemotherapy together in the treatment of advanced adenocarcinoma of the prostate by determination of the response rate, response duration, and duration of survival.

Technical Approach: All patients with histologically proven, asymptomatic or symptomatic Stage D adenocarcinoma of the prostate are eligible. Patients may not have had previous hormonal therapy or chemotherapy. They should have a life expectancy of 6 weeks or greater.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, 60 patients have been entered on this study. Response rates are high in both arms with 7/8 and 9/10 patients in each arm, respectively. The study will be amended to modify the parameters as well as to clarify patient eligibility (i.e., patients may begin endocrine therapy prior to randomization if randomization occurs within two weeks of the initiation of that therapy).

Detail Summary Sheet

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|--|----------|----------|-------------|---------|------------|
| Date: | 4 Jun 84 | Proj No: | SWOG 8223-5 | Status: | Terminated |
| Title: Master Protocol: Randomized Comparison of Drug Therapy for Squamous Cell Cancer of the Head and Neck with Early Assessment Phase II Agents, Phase III | | | | | |

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|---|-----------|--|--|
| Start Date | 12 Nov 82 | Est Comp Date: | |
| Principal Investigator J. Dean McCracken, M.D., COL, MC | | Facility Brooke Army Medical Center | |
| Dept/Svc Department of Medicine/Oncology | | Associate Investigators: James F. Boyd, M.D., LTC, MC | |
| Key Words: Squamous cell cancer of head and neck | | | |
| Accumulative MEDCASE Cost: | | Est Accumulative OMA Cost: | |
| Number of Subjects Enrolled During Reporting Period: <u>0</u> | | | |
| Total Number of Subjects Enrolled to Date: <u>0</u> | | | |
| Date of Periodic Review | | Results | |

Objective(s): 1) To estimate and compare response rates produced by the two combination regimens Arm I vs Arm II in all patients who receive either regimen (either at initial randomization or after re-randomization subsequent to failure on Arm III).

- 2) To estimate and compare response rates for those patients who receive either of the two combination regimens at initial randomization vs those patients who receive either of the two combination regimens after failure on Arm III. (The purpose of this comparison is to determine whether first use of Phase II agents alters patients' subsequent chances for remission induced by drugs of known activity.
- 3) To characterize toxicity experience on treatment Arms I, II, and for each agent in Arm III by type, severity, and frequency.
- 4) To characterize and compare survival experience for the groups described above.

Technical Approach: Patients must have a histologically proven advanced squamous cell carcinoma of the head and neck region which is not curable by other forms of therapy. They must have an objectively measurable tumor lesion(s) and a life expectancy of eight weeks or greater.

Progress: This study was closed because of poor patient accrual.

Detail Summary Sheet

Date: 12 Nov 84 Proj No: SWOG 8228 Status: Ongoing
 Title: Correlation Between Progesterone Receptor and Response to Tamoxifen in Patients with Newly Diagnosed Metastatic Breast Disease, Phase II

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|---|--|
| Start Date 12 Nov 82 | Est Comp Date: Unknown |
| Principal Investigator <u>James F. Boyd, M.D., LTC, MC</u> | Facility <u>Brooke Army Medical Center</u> |
| Dept/Svc <u>Department of Medicine/Oncology</u> | Associate Investigators: <u>Glenn M. Mills, M.D., MAJ, MC</u> |
| Key Words: <u>Tamoxifen</u> <u>Breast disease</u> | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | <u>2</u> |
| Total Number of Subjects Enrolled to Date: | <u>0</u> |
| Date of Periodic Review | Results |

Objective(s): To define the prognostic role of progesterone receptor in patients with newly diagnosed metastatic breast disease by correlating progesterone receptor levels with objective response rates in women treated with Tamoxifen.

Technical Approach: Female patients who have new, metastatic breast carcinoma are eligible for this study. Patients who have received prior hormonal adjuvant therapy are eligible, provided that they have not failed during therapy and the therapy has been stopped for at least three months. Patients must be ER+ in order to be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual has been slow due in part to the requirement for patients to have had estrogen and progesterone receptor assays performed in a designated laboratory. This problem has been reduced since the majority of the laboratories are presently on the designated list.

Detail Summary Sheet

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|--|---------------------------|------------------------|
| Date: 12 Nov 84 | Proj No: SWOG 8229 | Status: Ongoing |
| Title: Combined Modality Therapy for Multiple Myeloma, VMCP-VBAP for Remission | | |
| Induction Therapy: VMCP + Levamisole vs Sequential Half-Body Radiotherapy + Vincristine-Prednisone for Maintenance or Consolidation. Evaluation...Phase II | | |

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|---|--|
| Start Date 10 Dec 82 | Est Comp Date: Unknown |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Multiple myeloma | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 3 | |
| Total Number of Subjects Enrolled to Date: 5 | |
| Date of Periodic Review | Results |

Objective(s): 1) To compare the effectiveness of two intermittent pulse schedules of the chemotherapy combination of Vincristine, Melphalan, Cyclophosphamide and Prednisone (VMCP) plus Vincristine, BCNU, Adriamycin and Prednisone (VBAP) (alternating versus syncopated) for the induction of remissions in previously untreated patients with multiple myeloma.

- 2) For patients proven to achieve remission (at least 75% tumor regression after induction), to compare the value of 12 months of chemoimmunotherapy maintenance, VMCP + Levamisole, versus a consolidation program consisting of sequential half-body radiotherapy along with Vincristine and Prednisone followed by unmaintained remission.
- 3) For patients who only achieve improvement (50%-74% tumor regression) on chemotherapy induction, to determine whether sequential half-body radiotherapy along with Vincristine and Prednisone will increase the remission rate (at least 75% tumor regression).
- 4) To determine whether sequential half-body radiotherapy along with Vincristine and Prednisone can serve as an effective form of induction therapy for patients who fail to respond to chemotherapy or suffer early relapse.

Technical Approach: Only previously untreated patients with the diagnosis of multiple myeloma are eligible. This is a first-line study and only patients without prior cytotoxic chemotherapy are eligible.

Progress: Groupwide, patient accrual has been excellent. It is too early to report any meaningful results.

Detail Summary Sheet

Date: 12 Nov 84 Proj No: SWOG 8231 Status: Ongoing
 Title: Chemotherapy of Extragonadal Germinal Cell Neoplasms, Phase II

| | |
|--|---|
| Start Date 8 Jul 83 | Est Comp Date: Unknown |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Germinal cell neoplasm | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | 2 |
| Total Number of Subjects Enrolled to Date: | 3 |
| Date of Periodic Review | Results |

Objective(s): 1) To determine the effectiveness of alternating combination chemotherapy consisting of VBP (Vinblastine, Bleomycin and Cis-platinum) and EBAP (Bleomycin, Adriamycin, Cis-platinum and VP-16) in patients with metastatic germinal cell neoplasms arising in extragondal sites.

2) To determine the overall toxicity of the alternating combination of VBP and EBAP.

3) To determine the role of surgical removal of residual disease following this drug combination in partially responding patients.

4) To compare the response rates observed in this study with those reported by other investigators.

Technical Approach: Patients presenting with a histologically confirmed diagnosis of non-resectable extragonadal germ cell tumors are eligible for this study. All patients should have clearly measurable disease, or an abnormally elevated beta HCG and/or alpha fetoprotein. Patients with extragonadal seminomatous and non-seminomatous neoplasms will be eligible for treatment on this study, but will be analyzed separately.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual has been good. It is too early to report any meaningful results.

Detail Summary Sheet

| | | |
|--|--------------------|-----------------|
| Date: 12 Nov 84 | Proj No: SWOG 8232 | Status: Ongoing |
| Title: Treatment of Limited Small Cell Lung Cancer with VP16-/Cis-Platinum, Alternating with Vincristine/Adriamycin/Cyclophosphamide and Radiation Therapy vs Concurrent VP-16/Vincristine/Adriamycin...Radiation Therapy, Phase III | | |

| | |
|--|---|
| Start Date 14 Jan 83 | Est Comp Date: Unknown |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Limited small cell lung cancer | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 1 | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review Results | |

Objective(s): 1) To compare the efficacy of alternating non-cross-resistant, multidrug regimens with concurrent combination chemotherapy as remission induction in patients with limited small cell lung carcinoma.

2) To determine the toxicity of these treatment programs.

Technical Approach: All patients must have histologically proven small cell carcinoma of the lung. Prior to treatment, patients should be staged as to the extent of disease. Only patients with limited disease are eligible for this study. They must have evaluable or measurable disease. Patients having a prior surgical procedure are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide among 84 response evaluable patients 29 complete responses, 40 partial responses and 8 mixed responses have been observed.

Detail Summary Sheet

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|--|--------------------|-----------------|
| Date: 12 Nov 84 | Proj No: SWOG 8235 | Status: Ongoing |
| Title: Evaluation of Continuous Infusion Vinblastine in Gastric Carcinoma. | | |

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|--|---|
| Start Date 27 Jan 84 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Gastric carcinoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 1 | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review | Results |

Objective(s): 1) To determine the response rate, response duration, and duration of survival of gastric carcinoma treated with continuous infusion vinblastine.

2) To define the qualitative and quantitative toxicities of continuous infusion vinblastine administered in a Phase II study:

Technical Approach: Eligible patients must have a pathologically verified histologic diagnosis of adenocarcinoma of the stomach with gross unresectable residual disease. Both previously treated and untreated patients will be eligible for this study. Patients must have measurable disease and must not be receiving concomitant radiation therapy, hormonal therapy, or other chemotherapy.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

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|---|--------------------|-----------------|
| Date: 12 Nov 84 | Proj No: SWOG 8237 | Status: Ongoing |
| Title: Evaluation of Continuous Infusion Vinblastine Sulfate in Pancreatic Adenocarcinoma, Phase II | | |

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|--|---|
| Start Date 8 Jul 83 | Est Comp Date: Unknown |
| Principal Investigator James F. Boyd, M.D., COL, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Pancreatic adenocarcinoma | |
| Accumulative MEDCASE Cost: | Est Accumulative CMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 3 | |
| Total Number of Subjects Enrolled to Date: 4 | |
| Date of Periodic Review | Results |

Objective(s): To determine the clinical response rate of a five-day continuous infusion of vinblastine sulfate in pancreatic adenocarcinoma.

Technical Approach: To be eligible, patients must have a pathologically verified diagnosis of pancreatic adenocarcinoma. They must have objectively measurable or evaluable lesion(s) excluding CNS metastases and a life expectancy of at least eight weeks. Patients must have recovered from the toxicities of previous chemotherapy and/or radiotherapy and have demonstrated progressive disease.

Therapy will follow the schema outlined in the study protocol.

Progress: At this time, the data are too preliminary to report.

Detail Summary Sheet

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|--|--------------------|-----------------|
| Date: 12 Nov 84 | Proj No: SWOG 8239 | Status: Ongoing |
| Title: Evaluation of Spirogermanium in CNS Tumors, Phase II. | | |

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|--|---|
| Start Date 8 Apr 83 | Est Comp Date: Unknown |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: CNS tumors | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 1 | |
| Total Number of Subjects Enrolled to Date: 2 | |
| Date of Periodic Review Results | |

Objective(s): 1) To determine the antitumor activity of Spirogermanium in malignant gliomas by evaluation of response-rate.
 2) To determine the qualitative and quantitative toxicities of Spirogermanium given in a Phase II setting.
 3) To estimate the duration of survival experienced by these patients.

Technical Approach: Patients must have a histologically-confirmed diagnosis of astrocytomas, Grades III and IV; ependymoblastoma; medulloblastoma; or anaplastic oligodendrogloma. They must have failed primary surgical and/or radiation therapies and not be eligible for high priority protocols. All should have received adequate prior radiotherapy. All patients must have a measurable lesion by scan and a life expectancy of six weeks or more.

Therapy will follow the schema outlined in the study protocol.

Progress: Nineteen patients have been entered with one too early and eighteen fully or partially evaluable. Nine patients are evaluable for a response determination with one partial response and four improvements noted.

Detail Summary Sheet

Date: 13 Nov 84 Proj No: SWOG 8241 Status: Ongoing
 Title: Treatment for Advanced Non-Small Cell Lung Cancer: PVpvs PVpM vs PVe vs
 PVeMi vs FOMi/CAP, Phase III

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|--|---------------------------------|--|-------------------------------|
| Start Date | 11 Mar 83 | Est Comp Date: | Unknown |
| Principal Investigator | James F. Boyd, M.D., LTC, MC | Facility | Brooke Army Medical Center |
| Dept/Svc | Department of Medicine/Oncology | Associate Investigators: | Glenn M. Mills, M.D., MAJ, MC |
| Key Words: | Non-small cell lung cancer | | |
| Accumulative MEDCASE Cost: | | Est Accumulative CMA Cost: | |
| Number of Subjects Enrolled During Reporting Period: | 9 | Total Number of Subjects Enrolled to Date: | 10 |
| Date of Periodic Review | | Results | |

Objective(s): 1) To directly compare the efficacy and toxicity of Cis-platinum plus VP-16 (PVp) versus Cis-platinum plus Vinblastine (PVe) in patients with advanced (TNM Stage III M1) non-small cell lung cancer (NSCLC).

2) To compare the response rate, response duration, survival and toxicity of Cis-platinum plus VP-16 (PVp) to Cis-platinum plus VP16 plus MGBG (PVpM).

3) To compare the response rate, response duration, survival and toxicity of Cis-platinum plus Vinblastine (PVe) to Cis-platinum plus Vinblastine plus Mitomycin-C (PVeMi).

4) To re-evaluate and compare the activity of FOMi/CAP to PVp, PVpM, PVe and PVeMi using a five-arm, randomized study design.

5) To evaluate differences in response rates among patients with squamous cell carcinoma, adenocarcinoma or large cell undifferentiated carcinoma of the lung.

Technical Approach: All patients with a histologically or cytologically confirmed diagnosis of squamous cell carcinoma, adenocarcinoma or large cell carcinoma of the lung are eligible for this study. The patient's clinical presentation should be compatible with a neoplasm of bronchogenic origin.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time.

Detail Summary Sheet

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|---|--------------------|-----------------|
| Date: 13 Nov 83 | Proj No: SWOG 8244 | Status: Ongoing |
| Title: Clinical Antitumor Activity of Vinblastine Sulfate in Diffuse Mesothelioma, Phase II | | |

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|--|---|
| Start Date 10 Jun 83 | Est Comp Date: Unknown |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., LTC, MC |
| Key Words: Mesothelioma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 1 | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review | Results |

Objective(s): To determine the clinical response rate of five-day continuous infusion vinblastine sulfate in diffuse malignant mesothelioma.

Technical Approach: To be eligible, patients must have a pathologically verified diagnosis of mesothelioma. The mesothelioma may arise either in the thorax or abdomen, but must be of the diffuse malignant type (i.e., not locally resectable by surgery). Patients must have objectively measurable or evaluable lesion(s) excluding CNS metastases and a life expectancy of at least eight weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time.

Detail Summary Sheet

Date: 4 Jun 84 Proj No: SWOG 8245 Status: Completed
 Title: Combination Chemotherapy of Unfavorable Histology Non-Hodgkin's Lymphoma with CHOP and CVB (Alternating), Phase II

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|--|------------------------------|----------------|---------|
| Start Date | 11 Mar 83 | Est Comp Date: | Unknown |
| Principal Investigator | Facility | | |
| J. Dean McCracken, M.D., COL, MC | Brooke Army Medical Center | | |
| Dept/Svc | Associate Investigators: | | |
| Department of Medicine/Oncology | James F. Boyd, M.D., LTC, MC | | |
| Key Words: | | | |
| Non-Hodgkin's Lymphoma | | | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | | |
| Number of Subjects Enrolled During Reporting Period: 1 | | | |
| Total Number of Subjects Enrolled to Date: 3 | | | |
| Date of Periodic Review | Results | | |

Objective(s): 1) To gain experience with a treatment program utilizing a combination of two alternating non-cross resistant drug regimens in the treatment of "poor prognosis" lymphomas.

2) To determine an approximate complete remission rate to the Cyclophosphamide, Adriamycin, Vincristine, and Prednisone (CHOP)/Cis-platinum, Vinblastine, and Bleomycin (CVB) treatment program prior to initiating a group-wide phase III study utilizing this program.

Technical Approach: Biopsy proven previously untreated patients with Stage II-IV non-Hodgkin's lymphoma, "poor prognosis" histology (diffuse poorly differentiated lymphocytic lymphoma, diffuse histiocytic lymphoma, nodular histiocytic lymphoma, diffuse mixed lymphoma, undifferentiated lymphoma, lymphoblastic lymphoma, and immunoblastic sarcoma) will be eligible for treatment with this regimen.

Therapy will follow the schema outlined in the study protocol.

Progress: This study is closed to further patient registration. No reportable data are available.

Detail Summary Sheet

Date: 13 Nov 84 Proj No: SWOG 8263 Status: Ongoing
 Title: Combined Radiation Therapy and Chemotherapy as Adjuvant Treatment for Duke's B2-C Colon Cancer, Phase I-II, Pilot

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|--|---------------------------------|--------------------------|-------------------------------|
| Start Date | 8 Jul 83 | Est Comp Date: | Unknown |
| Principal Investigator | James F. Boyd, M.D., LTC, MC | Facility | Brooke Army Medical Center |
| Dept/Svc | Department of Medicine/Oncology | Associate Investigators: | Glenn M. Mills, M.D., MAJ, MC |
| Key Words: | Duke's B2-C colon cancer | | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | | |
| Number of Subjects Enrolled During Reporting Period: | 2 | | |
| Total Number of Subjects Enrolled to Date: | 3 | | |
| Date of Periodic Review | Results | | |

Objective(s): To determine the immediate and delayed toxicity of two adjuvant therapy programs for patients with Dukes B2-C colon cancer: intravenous bolus 5-fluorouracil and whole abdominal radiation therapy begun simultaneously four to six weeks postoperatively.

Technical Approach: Patients must have a histologically confirmed diagnosis of Duke's C1 (limited to the serosa with positive nodes) or C2 (extension through the serosa with positive nodes). Patients entering the study postoperatively must have an adequate surgical procedure of the tumors of the cecum and ascending colon, proximal transverse colon, splenic flexure or descending colon, or sigmoid. They must not have had any prior malignancies, inflammatory bowel disease or liver disease. Patients may not have received prior radiation therapy or chemotherapy.

Therapy will follow the schema outlined in the study protocol.

Progress: Twenty-seven patients have been registered on this study. With median follow-up time of 5 months, no patient has relapsed.

Detail Summary Sheet

Date: 4 Jun 84 Proj No: SWOG 8264 Status: Completed
 Title: Combination Chemotherapy with m-AMSA, Cis-Platinum and MGBG for Refractory Lymphoma, Phase II

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|--|---|
| Start Date 8 Jul 83 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Refractory lymphomas | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review Results | |

Objective(s): 1) To determine if the three drug combination of methanesulfonamide N-4-(9-acridinyl-amino)-3-methoxyphenyl (m-AMSA), and methyl-glyoxal bis-guanylhydrazone (MGBG) has reasonable activity in patients with refractory unfavorable histology lymphomas; response rate and response duration will be assessed also.

2) To determine the toxicities of this combination of drugs.

Technical Approach: Eligible patients must have histologically confirmed, unfavorable histology, non-Hodgkin's lymphomas refractory to standard chemotherapy regimens. They must have measurable disease and a life expectancy of at least eight weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Among the patients with unfavorable history, 25 are currently partially evaluable. Of those, there has been one complete response lasting 11+ months and nine partial responses. Therefore, the PR + CR is 40%.

Detail Summary Sheet

| | | |
|---|--------------------|-----------------|
| Date: 13 Nov 84 | Proj No: SWOG 8269 | Status: Ongoing |
| Title: Concurrent Chemo-Radiotherapy for Limited Small Cell Carcinoma of the Lung, Phase II - Pilot | | |

| | |
|---|--|
| Start Date 8 Oct 82 | Est Comp Date: Unknown |
| Principal Investigator <u>James F. Boyd, M.D., LTC, MC</u> | Facility <u>Brooke Army Medical Center</u> |
| Dept/Svc <u>Department of Medicine/Oncology</u> | Associate Investigators: <u>Glenn M. Mills, M.D., MAJ, MC</u> |
| Key Words: <u>Small cell carcinoma of lung</u> | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: <u>5</u> | |
| Total Number of Subjects Enrolled to Date: <u>10</u> | |
| Date of Periodic Review _____ Results _____ | |

Objective(s): 1) To explore the response rate with the concurrent use of radiation therapy plus chemotherapy utilizing Cis-platinum VP-16 and Vincristine in limited small cell carcinoma of the lung.

2) To observe the toxicities of this combined modality program.

Technical Approach: Patients with a histologically or cytologically proven diagnosis of small cell carcinoma of the lung will be eligible for this study. All patients must have so-called "limited disease". This is defined as disease confined to one hemithorax, mediastinum, hilar and supraclavicular areas, which could be encompassed within a single radiation therapy port. Patients having had surgical diagnostic or therapeutic techniques are eligible, except if all gross evidence of disease has been removed after surgical resection.

Therapy will follow the schema outlined in the study protocol.

Progress: Five complete responses and six partial responses have been seen in eleven response-evaluable patients.

Detail Summary Sheet

| | | |
|--|---------------------------|------------------------|
| Date: 13 Nov 84 | Proj No: SWOG 8291 | Status: Ongoing |
| Title: The Intergroup Adult Adjuvant Soft Tissue Sarcoma Study #1. A Randomized Trial of Adjuvant Doxorubicin (Adriamycin) versus Standard Therapy (A Delay of Chemotherapy Until the Time of Possible Relapse) | | |

| | |
|---|--|
| Start Date 11 Mar 83 | Est Comp Date: Unknown |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Soft tissue sarcoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 1 | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review | Results |

Objective(s): This prospective randomized study is designed to evaluate the efficacy of adjuvant Adriamycin compared to standard treatment (a delay of chemotherapy until the time of demonstrated relapse) in the management of patients with Stages IIB, IIIA-C and tissue sarcoma in terms of local recurrence rate, disease-free interval, and survival.

Technical Approach: For inclusion in this study, patients must have a histopathologically proven diagnosis of soft tissue sarcoma Stages IIB, IIIA-C, and IVA. The tumor may be either previously untreated or a local recurrence.

Therapy will follow the schema outlined in the study protocol.

Progress: No meaningful data are available.

Detail Summary Sheet

Date: 13 Nov 84 Proj No: SWOG 8292 Status: Ongoing
 Title: Treatment for Brain Metastases, Phase III. Intergroup Study

| | |
|--|---|
| Start Date 8 Apr 83 | Est Comp Date: Unknown |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Brain metastases | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 1 | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review _____ Results _____ | |

Objective(s): 1) To test whether the addition of surgery before radiation therapy is a significant improvement over radiation therapy alone in the treatment of patients with apparent single brain metastases. Endpoints studied will be:

One year survival rates and median survival times.

Local control rates of brain metastases one month and six months after treatment.

Improvement of neurological deficit as measured by the percentage of patients with improved neurological function.

2) To evaluate patient refusal with respect to the surgical component.

Technical Approach: All patients having histologically confirmed cancer with evidence of a potentially resectable single intracranial mass lesion as documented by a contrast-enhanced CAT scan are eligible. Only patients with apparently resectable cerebellar or cerebral cortex lesions will be eligible. Patients with bronchogenic carcinoma should have control of the primary tumor and no other metastases prior to admission on this study.

Progress: Patient accrual has been extremely slow. No reportable data are available.

Detail Summary Sheet

Date: 13 Nov 84 Proj No: SWOG 8293 Status: Ongoing
 Title: Intergroup Phase III Protocol for the Management of Locally or Regionally Recurrent but Surgically Resectable Breast Cancer.

| | |
|--|---|
| Start Date 25 May 84 | Est Comp Date: Unknown |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Breast cancer | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review Results | |

Objective(s): 1) To better define the relative roles of systemic and local treatments in the care of resectable locally or regionally recurrent cancer of the breast in patients who have no evidence of disease after resection.
 2) To assess the effects of chemotherapy, radiation therapy, singly or in combination, administered immediately after surgical resection on control, disease-free interval and pattern of re-recurrence.
 3) To determine the effects of the administration of systemic chemotherapy or radiation therapy which has been delayed until local, regional, re-recurrence upon local and regional control, disease-free survival, patterns of relapse, and survival.

Technical Approach: To be eligible, patients must have undergone a surgical resection with tumor-free margins leaving the patient clinically free of disease less than 6 weeks prior to entry into the study. Patients must have histologically proven technically resectable locally or regionally recurrent breast cancer, the primary of which was initially treated by surgery without postoperative irradiation.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

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|-----------------|--------------------|-----------------|
| Date: 13 Nov 84 | Proj No: SWOG 8294 | Status: Ongoing |
|-----------------|--------------------|-----------------|

Title: Evaluation of Adjuvant Therapy and Biological Parameters in Node Negative Operable Female Breast Cancer (ECOG EST-1180), Intergroup, Study (Observation Only) (Patients Randomized to CMFP Chemotherapy)

| | |
|--|---|
| Start Date 11 Mar 83 | Est Comp Date: Unknown |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Breast cancer | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | 12 |
| Total Number of Subjects Enrolled to Date: | 12 |
| Date of Periodic Review | Results |

Objective(s): 1) To assess the impact of short-term intensive chemotherapy with CMFP to prevent disease recurrence and prolong survival in N- patients with any size ER- tumor and N- patients with ER+ tumors whose pathological size is greater than or equal to 3 cm.

2) To assess the impact of surgical procedures, ER status, menopausal status and tumor size.

3) To develop guidelines referable to histopathological features of N- tumors which are reproducible and assess their prognostic impact for disease-free survival and survival.

4) To assess the value to CEA in predicting recurrence and survival rates.

5) To assess the natural history of a subgroup with N-, ER+ small tumors.

Technical Approach: All female patients having had at least a total mastectomy with an axillary dissection or total mastectomy with low axillary dissection for potentially curable breast carcinoma as defined in this protocol and having no histopathological evidence of axillary node involvement will be considered for inclusion in this study.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time.

Detail Summary Sheet

| | | |
|---|--------------------|-----------------|
| Date: 1 Oct 84 | Proj No: SWOG 8302 | Status: Ongoing |
| Title: Phase II Study of Doxorubicin, Mitomycin-C and 5-Fluouracil in the Treatment of Metastatic Adenocarcinoma of the Prostate. | | |

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|--|---|
| Start Date 4 Nov 83 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Adenocarcinoma Prostate | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 2 | |
| Total Number of Subjects Enrolled to Date: 2 | |
| Date of Periodic Review | Results |

Objective(s): To test the effectiveness and toxicity of DMF (Doxorubicin, Mitomycin-C, and 5-Fluorouracil) in the treatment of Stage D₂ adenocarcinoma of the prostate.

Technical Approach: Patients with histologically proven, metastatic adenocarcinoma of the prostate with measurable disease are eligible. Patients with blastic bone lesions on x-ray as a sole manifestation of metastases are not eligible. However, patients with bone metastases only who have positive bone scans will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, 29 patients have been entered. Six are currently evaluable with two partial responses reported.

Detail Summary Sheet

Date: 13 Nov 84 Proj No: SWOG 8303 Status: Ongoing
 Title: Evaluation of 2'Deoxycoformycin in Refractory Multiple Myeloma, Phase II

| | |
|--|---|
| Start Date 8 Jul 83 | Est Comp Date: Unknown |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Multiple myeloma | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 1 | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review Results | |

Objective(s): 1) To determine the response rate and response duration of refractory multiple myeloma treated with low dose 2'Deoxycoformycin used in a single dose, every two week schedule.

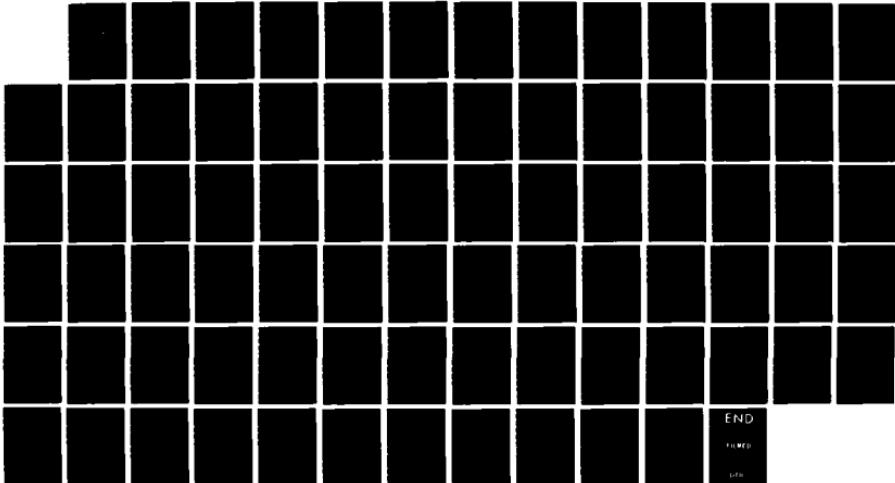
2) To define the qualitative and quantitative toxicities of 2'Deoxycoformycin administered in a Phase II study.

Technical Approach: 2'Deoxycoformycin is intended for therapy of patients with multiple myeloma who have had prior exposure to and progression of disease on protocols of higher priority. All patients must have a pathologically verified histologic diagnosis of multiple myeloma. Only symptomatic patients or those with demonstrated progressive disease are eligible.

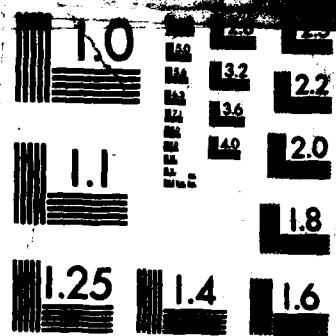
Therapy will follow the schema outlined in the study protocol.

Progress: The dose schedule utilized in this study has proven to be extremely safe for patients with good renal function. Enthusiasm with this agent is now clear cut.

RD-A157 443 DEPARTMENT OF CLINICAL INVESTIGATION ANNUAL RESEARCH 2/2
PROGRESS REPORT FISCAL YEAR 1984 VOLUME 2(U) BROOKE
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Detail Summary Sheet

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|--|--------------------|-----------------|
| Date: 13 Nov 84 | Proj No: SWOG 8304 | Status: Ongoing |
| Title: Evaluation of L-Alanosine in Metastatic Carcinoma of the Breast | | |

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|--|---|
| Start Date 8 Jul 83 | Est Comp Date: Unknown |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Metastatic carcinoma of breast | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 2 | |
| Total Number of Subjects Enrolled to Date: 3 | |
| Date of Periodic Review | Results |

Objective(s): 1) To determine the antitumor activity as determined by response rate and duration of response of L-Alanosine used on a three day, every three week schedule in patients with metastatic carcinoma of the breast who have failed on standard therapy.

2) To determine the nature and degree of toxicity of L-Alanosine.

Technical Approach: All patients with metastatic carcinoma of the breast resistant to standard chemotherapeutic agents are eligible. Patients must have measurable or evaluable disease and a life expectancy of at least nine weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. It is still too early to report any meaningful results.

Detail Summary Sheet

Date: 13 Nov 84 Proj No: SWOG 8305 Status: Ongoing
 Title: Chemotherapy of Metastatic Colorectal Carcinoma with 5-FU and Folinic Acid, Phase II

| | |
|--|---|
| Start Date 8 Jul 83 | Est Comp Date: Unknown |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Colorectal carcinoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | 1 |
| Total Number of Subjects Enrolled to Date: | 6 |
| Date of Periodic Review | Results |

Objective(s): 1) To determine the toxicity of 5-fluorouracil (5-FU) and folinic acid (CF) therapy in patients with metastatic colorectal carcinoma.
 2) To determine the response-rate in previously untreated patients receiving 5-FU and folinic acid.

Technical Approach: Patients must have clinically measurable disease to qualify for this study. They must have biopsy-proven adenocarcinoma arising from the colon or rectum. Obstructive lesions in the colon and rectum must have been bypassed or adequately maintained by decompression measures.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual has been good. Eight patients are fully evaluable with two partial responses observed.

Detail Summary Sheet

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|---|--------------------|-----------------|
| Date: 13 Nov 84 | Proj No: SWOG 8308 | Status: Ongoing |
| Title: Combination of Cis-Platinum and Dichloromethotrexate in Patients with Advanced Bladder Cancer, Phase II. | | |

| | |
|--|---|
| Start Date 27 Jan 84 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Bladder cancer | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review n/a | Results |

Objective(s): 1) To obtain data regarding the activity and toxicity of combination cis-platinum and dichloromethotrexate in patients with objectively measurable metastatic transitional cell carcinoma of the bladder who have good renal function and who have not previously received chemotherapy.

2) To investigate the single agent activity and toxicity of dichloromethotrexate in previously untreated patients with impaired renal function.

Technical Approach: Eligible patients must have a histologically confirmed diagnosis of metastatic transitional cell carcinoma of the urothelium. Only patients without prior systemic chemotherapy are eligible for this study. Patients with prior radiotherapy are eligible if the disease has progressed, if at least six weeks have elapsed since completion of the radiotherapy (non-cranial) and if measurable sites of disease exist outside of the previous radiation field.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

| | | | | | |
|---|-----------|----------|-----------|---------|---------|
| Date: | 13 Nov 84 | Proj No: | SWOG 8311 | Status: | Ongoing |
| Title: Combination Chemotherapy with Cis-Platinum, Vinblastine, and Methylglyoxal Bis (Guanylhydrazone) (MGBG) in Epidermoid Carcinoma of the Esophagus | | | | | |

| | | | |
|--|-------------------------------|----------------|---------|
| Start Date | 9 Sep 83 | Est Comp Date: | Unknown |
| Principal Investigator | Facility | | |
| James F. Boyd, M.D., LTC, MC | Brooke Army Medical Center | | |
| Dept/Svc | Associate Investigators: | | |
| Department of Medicine/Oncology | Glenn N. Mills, M.D., MAJ, MC | | |
| Key Words: | | | |
| Epidermoid carcinoma | | | |
| Accumulative MEDCASE | Est Accumulative | | |
| Cost: | OMA Cost: | | |
| Number of Subjects Enrolled During Reporting Period: 0 | | | |
| Total Number of Subjects Enrolled to Date: 1 | | | |
| Date of Periodic Review _____ Results _____ | | | |

Objective(s): 1) To define the response rate and duration, as well as survival duration, in patients with advanced epidermoid carcinoma of the esophagus when treated with Cis-platinum, Vinblastine and MGBG.

2) To determine the toxicity of this regimen in the treatment of epidermoid carcinoma of the esophagus.

Technical Approach: All patients must have measurable disease and must have histologically or cytologically confirmed diagnosis of epidermoid carcinoma of the esophagus.

Therapy will follow the schema outlined in the study protocol.

Progress: Data are too preliminary to report at this time.

Detail Summary Sheet

Date: 5 Sep 84 **Proj No:** SWOG 8312 **Status:** Ongoing
Title: Megestrol Acetate and Aminoglutethimide/Hydrocortisone in Sequence or in Combination as Second-Line Endocrine Therapy of Estrogen Receptor Positive Metastatic Breast Cancer, Phase III

| | |
|---|--|
| Start Date 31 Aug 84 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Breast cancer | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review n/a | Results |

Objective(s): 1) To determine whether combination hormonal therapy with Aminoglutethimide and Hydrocortisone (AH) plus Megestrol Acetate (M), agents thought to have different mechanisms of action, offers an improved response rate with prolonged response duration and increased patient survival over the sequential use of each agent in Estrogen Receptor (ER) positive patients who have progressed after responding to primary hormonal treatment with Tamoxifen.

- 2) To assess the relative toxicities of Megestrol Acetate and medical adrenalectomy.
- 3) To assess the value of progesterone receptor (PgR) in predicting subsequent responses to a variety of hormonal therapies.

Technical Approach: Postmenopausal female patients with progressive, measurable metastatic breast carcinoma are eligible. Patients must have received an adequate trial of tamoxifen therapy and achieved at least a partial response in all areas of measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 5 Sep 84 Proj No: SWOG 8313 Status: Ongoing
 Title: Multiple Drug Adjuvant Chemotherapy for Patients with ER Negative Stage II Carcinoma of Breast, Phase III.

| | |
|--|---|
| Start Date 31 Aug 84 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Breast carcinoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review n/a | Results |

Objective(s): 1) To compare through a randomized prospective study, the recurrence rates and disease-free intervals (DFI) for postoperative axillary node positive estrogen receptor negative (ER-) breast cancer patients given adjuvant therapy with either short term intense chemotherapy (FAC-M) or one year standard chemotherapy (CMFVP).

- 2) To compare the effect of these two adjuvant therapies on survival.
- 3) To compare the relative toxicity of the two therapies.

Technical Approach: All patients must have histologically proven breast carcinoma with metastases to one or more axillary nodes to be eligible. Only patients with ER- breast carcinoma are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 22 Aug 84 Proj No: SWOG 8316 Status: Ongoing
 Title: Evaluation of Fludarabine Phosphate (NSC-312887) in Renal Cell Carcinoma, Phase II.

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|---|---|
| Start Date 22 Aug 84 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Fludarabine phosphate Renal cell carcinoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review _____ Results _____ | |

Objective(s): 1) To determine the response rate and remission duration of renal cell carcinoma when treated with Fludarabine Phosphate.

2) To define the qualitative and quantitative toxicities of Fludarabine Phosphate administered in a Phase II study.

Technical Approach: Eligible patients must have a histologically confirmed diagnosis of renal cell carcinoma and no be eligible for Southwest Oncology Group protocols of higher priority. Only patients who have received no prior chemotherapy regimens will be eligible. Patients must have clearly measurable disease and a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

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|---|--------------------|-----------------|
| Date: 5 Sep 84 | Proj No: SWOG 8319 | Status: Ongoing |
| Title: Evaluation of Fludarabine Phosphate in Ovarian Cancer, Phase II. | | |

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|--|---|
| Start Date 31 Aug 84 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Cancer, ovarian | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review | Results |

Objective(s): 1) To determine the antitumor activity of Fludarabine Phosphate (2-Fluoro-ara-AMP) in patients with metastatic or recurrent epithelial carcinomas of the ovary who have failed on higher priority treatment protocols.

2) To determine the nature and degree of toxicity of Fludarabine Phosphate.

Technical Approach: All patients not eligible for higher priority studies with histologically proven incurable advanced metastatic or recurrent epithelial carcinoma of the ovary are eligible. All patients must have failed primary chemotherapy regimens and have a life expectancy of at least six weeks.

Progress: This is a new study.

Detail Summary Sheet

Date: 5 Sep 84 Proj No: SWOG 8320 Status: Ongoing
 Title: Evaluation of Fludarabine Phosphate in Endometrial Cancer, Phase II.

| | |
|--|---|
| Start Date 31 Aug 84 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Cancer, endometrial | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review n/a | Results _____ |

Objective(s): 1) To determine the antitumor activity of Fludarabine Phosphate in patients with metastatic or recurrent epithelial carcinomas of the endometrium who have failed on higher priority treatment protocols.

2) To determine the nature and toxicity of Fludarabine Phosphate.

Technical Approach: All patients not eligible for higher priority Southwest Oncology Group studies with histologically proven incurable advanced metastatic or recurrent epithelial carcinoma of the endometrium are eligible. Patients must have a life expectancy of six weeks and clearly measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 5 Sep 84 **Proj No:** SWOG 8322 **Status:** Ongoing
Title: Evaluation of Fludarabine Phosphate in Advanced Sarcomas, Phase II.

| | |
|---|--|
| Start Date 31 Aug 84 | Est Comp Date: _____ |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Sarcoma | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: _____ |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review n/a | Results _____ |

Objective(s): 1) To determine the response rate and response duration of advanced sarcomas treated with fludarabine phosphate.

2) To define the qualitative and quantitative toxicities of fludarabine phosphate administered in a Phase II study.

Technical Approach: To be eligible, all patients must have a pathologically verified histologic diagnosis of sarcoma. Patients must have measurable disease and must not be receiving concomitant radiation, hormonal or chemotherapy.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

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|---|--------------------|-----------------|
| Date: 5 Oct 84 | Proj No: SWOG 8323 | Status: Ongoing |
| Title: Evaluation of Fludarabine Phosphate in Advanced Mycosis Fungoides, Phase II. | | |

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| Start Date 28 Sep 84 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Broke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Mycosis fungoides | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review n/a Results

Objective(s): 1) To determine the response-rate and remission duration of treatment with low dose fludarabine phosphate used on an every three-week schedule in advanced mycosis fungoides.

2) To define the qualitative and quantitative toxicities of the drug when administered in a Phase II study.

Technical Approach: Patients must have advanced mycosis fungoides with at least extensive plaque disease, or skin nodules, gross skin tumor, lymph node involvement or extranodal involvement. All patients must have measurable disease clearly documented prior to initiation of therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

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|--|--------------------|-----------------|
| Date: 13 Nov 84 | Proj No: SWOG 8325 | Status: Ongoing |
| Title: Combination Chemotherapy with Mitotane (O,P'-DDD) and Cis-Platinum in Metastatic Adrenal Carcinoma, Phase II. | | |

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|--|---|
| Start Date 2 May 84 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Adrenal carcinoma | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review _____ Results _____ | |

Objective(s): 1) To study the responsiveness of adrenocortical carcinoma to combination chemotherapy consisting of Cis-Platinum (DDP) and Mitotane (O,P'DDD).

- 2) To study the prognostic features of patients with metastatic and/or unresectable adrenal carcinoma receiving chemotherapy.
- 3) To document the toxicity of chemotherapy in this group of patients.

Technical Approach: Patients with metastatic or residual adrenocortical carcinoma in whom further surgical removal of disease is not possible will be eligible. Prior treatment with O,P'-DDD or radiotherapy is allowed. Prior chemotherapy with agents other than cis-platinum is also acceptable.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 5 Sep 84 **Proj No:** SWOG 8328 **Status:** Ongoing
Title: Evaluation of Fludarabine Phosphate in Cervical Cancer, Phase II.

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|---|--|
| Start Date 31 Aug 84 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Cancer, cervical | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | 0 |
| Total Number of Subjects Enrolled to Date: | 0 |
| Date of Periodic Review n/a | Results |

Objective(s): 1) To determine the antitumor activity of Fludarabine Phosphate in patients with metastatic or recurrent epithelial carcinomas of the cervix who have failed on higher priority treatment protocols.

2) To determine the nature and degree of toxicity of Fludarabine Phosphate.

Technical Approach: All patients not eligible for higher priority Southwest Oncology Group studies with histologically proven incurable advanced metastatic or recurrent epithelial carcinoma of the cervix are eligible. Patients must have measurable disease and a life expectancy of six weeks.

Progress: This is a new study.

Detail Summary Sheet

| | | |
|--|---|-----------------|
| Date: 13 Nov 84 | Proj No: SWOG 8360 | Status: Ongoing |
| Title: Use of the Surgically Implanted "Infusaid" Pump for Ambulatory Outpatient Hepatic Arterial Chemotherapy for Patients with Colon Cancer Metastatic to the Liver, Phase II - Pilot | | |
| Start Date 13 May 83 Principal Investigator James F. Boyd, M.D., LTC, MC Dept/Svc Department of Medicine/Oncology Key Words: Infusaid pump Colon cancer Hepatic arterial chemotherapy | Est Comp Date: Unknown Facility Brooke Army Medical Center Associate Investigators: Glenn M. Mills, M.D., MAJ, MC | |
| Accumulative MEDCASE Cost: Number of Subjects Enrolled During Reporting Period: 5 Total Number of Subjects Enrolled to Date: 6 Date of Periodic Review | Est Accumulative OMA Cost: Results | |

Objective(s): 1) To determine the response rate, disease-free interval and survival in patients with colon carcinoma metastatic to the liver treated using the "Infusaid" pump with continuous intrahepatic arterial infusions of 5-FUDR and monthly cis-platinum injections via the side port.

2) To determine the feasibility of utilizing the "Infusaid" pump to deliver intraarterial chemotherapy in a cooperative group setting.

Technical Approach: To be eligible for inclusion on this study, patients must have a biopsy-proven colorectal cancer metastatic to the liver as the primary factor determining their survival and quality of life. Patients will be stratified for hepatic-only versus extra-hepatic disease at the time of registration. Patients must have an estimated survival of greater than 60 days.

Therapy will follow the schema outlined in the study protocol.

Progress: Of the 30 evaluable patients, 15 or 50% have responded, 1 CR and 14 PR's.

Detail Summary Sheet

Date: 14 Nov 84 Proj No: SWOG 8364 Status: Ongoing
 Title: Immediate Postoperative Adjuvant Chemotherapy in Patients with Operable Breast Cancer, Phase II-Pilot.

| | |
|--|---|
| Start Date 10 Feb 84 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Breast cancer | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | 3 |
| Total Number of Subjects Enrolled to Date: | 3 |
| Date of Periodic Review | Results |

Objective(s): To assess the toxicity of immediate chemotherapy with Cyclophosphamide, Methotrexate, 5-Fluorouracil, Vincristine and Prednisone beginning at the time of surgery in patients with Stage II carcinoma of the breast.

Technical Approach: All female patients with biopsy proven disease of breast cancer which appears to be operable and patients with clinical T₁₋₃N₀₋₁ are eligible. Patients may receive radical, modified radical, total mastectomy, or lumpectomy and axillary node dissection or segmental mastectomy plus axillary node dissection. Patients receiving mastectomy other than segmental or lumpectomy may electively receive radiation therapy at the discretion of the treating physician.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. It is too early to report any meaningful results.

Detail Summary Sheet

| | | |
|---|--------------------|-----------------|
| Date: 14 Nov 84 | Proj No: SWOG 8386 | Status: Ongoing |
| Title: Evaluation of Fludarabine Phosphate in Colorectal Carcinoma, Phase II. | | |

| | |
|--|---|
| Start Date 2 May 84 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Colorectal carcinoma | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 2 | |
| Total Number of Subjects Enrolled to Date: 2 | |
| Date of Periodic Review | Results |

Objective(s): 1) To determine the antitumor activity of Fludarabine Phosphate in patients with colorectal by determination of the response-rate and remission duration.

2) To further define the qualitative and quantitative toxicities of this drug in a Phase II study.

Technical Approach: Patients must have clinically measurable recurrent or disseminated disease to qualify for the study. Patients must have a life expectancy of at least ten weeks. Patients must not have received any prior chemotherapy and must not be receiving concomitant radiation therapy or hormonal therapy while on this study.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 13 Nov 84 Proj No: SWOG 8391 Status: Ongoing
 Title: The Intergroup Adult Adjuvant Soft Tissue Sarcoma Study Protocol #2: A Randomized Trial of Adjuvant Doxorubicin (Adriamycin) vs Standard Therapy.

| | |
|--|---|
| Start Date 10 Jun 83 | Est Comp Date: Unknown |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Soft tissue sarcoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review Results | |

Objective(s): 1) To evaluate the effectiveness of adjuvant chemotherapy in improving the local control rate in inoperable, unresectable or incompletely resected soft tissue sarcomas treated with radiotherapy.

2) To determine the effect of adjuvant chemotherapy on the incidence of metastases, disease-free interval and survival.

3) To evaluate tolerance (with emphasis on local tissue tolerance in the irradiated area) to combined chemotherapy and radiation therapy.

Technical Approach: Eligible patients must have histopathologically proven diagnosis of soft tissue sarcoma. Patients with localized sarcomas, newly diagnosed or recurrent after previous surgery who are not candidates for curative surgical resection, or who have residual tumor following an incomplete surgical resection will be candidates for the study.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time.

Detail Summary Sheet

| | | |
|---|---|-----------------|
| Date: 14 Nov 84 | Proj No: SWOG 8393 | Status: Ongoing |
| Title: MEL 82 323, National Intergroup Protocol for Intermediate Thickness Melanoma 1.0 to 4.0 MM - Evaluation of Optimal Surgical Margins (2 vs 4 cm) Around the Primary Melanoma and Evaluation of Elective Regional Lymph Node Dissection. | | |
| Start Date 13 Jan 84 | Est Comp Date: | |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center | |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC | |
| Key Words: Melanoma | | |
| Accumulative MEDCASE | Est Accumulative | |
| Cost: | OMA Cost: | |
| Number of Subjects Enrolled During Reporting Period: 0 | | |
| Total Number of Subjects Enrolled to Date: 0 | | |
| Date of Periodic Review Results | | |

Objective(s): 1) To determine the safest excision margins around the primary melanoma.
 2) To evaluate the management of the regional lymph nodes (immediate vs delayed lymphadenectomy).
 3) To evaluate the relative prognostic value of various histopathological parameters of melanoma.

Technical Approach: Patients with primary malignant melanomas of the skin measuring 1.0 to 4.0 mm thick with clinical stage I disease will be eligible for this trial. Patient must have a life expectancy of at least ten years from the time of diagnosis to permit long-term evaluation and follow-up.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 5 Sep 84 Proj No: SWOG 8461 Status: Ongoing
 Title: Registration and Evaluation of Patients Aged 55 and Over with
 Unfavorable Histology NHL, Phase II, Pilot

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|--|--|
| Start Date 31 Aug 84 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, M |
| Key Words: Non-Hodgkin's Lymphoma | |
| Accumulative MEDCASE Cost: | Est Accumulative CMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 3 | |
| Total Number of Subjects Enrolled to Date: 3 | |
| Date of Periodic Review n/a | Results |

Objective(s): 1) To determine the number of patients aged 55 and over with unfavorable histology non-Hodgkin's lymphoma who are treated at the participating institutions.

- 2) To determine the number of patients not entered on Southwest Oncology Group treatment protocols and the reasons why.
- 3) To compile baseline information on the natural history of such patients.
- 4) To evaluate the quality of life of these patients.

Technical Approach: Patients with Stage II-IV, histologically proven "poor prognosis" non-Hodgkin's lymphoma will be eligible. Patients must be age 55 or over.

Progress: It is too early to report any meaningful results.

Detail Summary Sheet

Date: 17 Jul 84 Proj No: SWOG 8490 Status: Ongoing
 Title: Phase II Study of PAC (Cis-Platinum, Adriamycin, and Cyclophosphamide) in Treatment of Invasive Thymoma, Intergroup Study.

| | |
|--|---|
| Start Date 17 Jul 84 | Est Comp Date: |
| Principal Investigator James F. Boyd, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Medicine/Oncology | Associate Investigators: Glenn M. Mills, M.D., MAJ, MC |
| Key Words: Thymoma | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review _____ Results _____ | |

Objective(s): 1) To determine the objective response rate in extensive and limited invasive thymoma treated with PAC.

2) To determine the duration of remission of patients with limited invasive thymoma treated with split course radiotherapy plus PAC and in patients with extensive disease treated with PAC alone.

Technical Approach: Eligible patients must have locally invasive, recurrent or metastatic thymoma and at least one bidimensional measurable lesion.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

| | | |
|--|-----------------|----------------|
| Date: 31 Oct 84 | Proj No: GOG 20 | Status: Closed |
| Title: A Randomized Comparison of Adriamycin vs No Further Therapy in Patients with Uterine Sarcomas, Stage I and II, Phase III. | | |

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| Start Date FY 81 | Est Comp Date: |
| Principal Investigator (vice Capen) Danny R. Barnhill, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Obstetrics-Gynecology | Associate Investigators: |
| Key Words: Sarcoma, uterine | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review | Results |

Objective(s): To determine if adjuvant chemotherapy will improve the cure rate in uterine sarcomas, Stage I and II.

Technical Approach: Patients with histologically proven sarcomas of the uterine corpus will be considered if they have Stage I or Stage II disease clinically, and if they have no known gross residual disease following surgery. Preoperative or postoperative pelvic radiotherapy may be given at the discretion of the principal investigator, but a decision about this mode of therapy must be made prior to the chemotherapy randomization.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient remains on this study and will continue therapy as outlined in the study protocol. However, the study has been closed to new entries.

Detail Summary Sheet

| | | |
|--|-----------------|----------------|
| Date: 1 Nov 84 | Proj No: GOG 24 | Status: Closed |
| Title: Treatment of Women with Cervical Cancer Stage IIB, IIIB, IVA, Confined to the Pelvis and/or Para-Aortic Nodes with Radiotherapy Alone vs Radiotherapy Plus Immunotherapy, Phase II. | | |

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|---|----------------------------|
| Start Date FY 78 | Est Comp Date: |
| Principal Investigator <u>Danny R. Barnhill, M.D., MAJ, MC</u> | Facility |
| Dept/Svc <u>Department of Obstetrics-Gynecology</u> | Associate Investigators: |
| Key Words: Cancer, cervical | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | 0 |
| Total Number of Subjects Enrolled to Date: | 0 |
| Date of Periodic Review | Results |

Objective(s): To assess the therapeutic effectiveness of immunotherapy (intravenous C-parvum) used concomitantly with radiation in patients with advanced carcinoma of the uterine cervix.

Technical Approach: Patients with histologically confirmed, previously untreated carcinoma of the uterine cervix (adenocarcinoma or squamous carcinoma) are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study. The study has been closed by GOG.

Detail Summary Sheet

| | | |
|--|-----------------|----------------|
| Date: 1 Nov 84 | Proj No: GOG 25 | Status: Closed |
| Title: A Randomized Comparison of Melphalan Therapy Alone vs Melphalan plus Immunotherapy (C. Parvum) in the Treatment of Women with Stage III (Optimal) Epithelial Carcinoma of the Ovary (Phase II). | | |

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| Start Date FY 78 | Est Comp Date: |
| Principal Investigator Danny R. Barnhill, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Obstetrics-Gynecology | Associate Investigators: |
| Key Words: Carcinoma, epithelial | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review | Results |

Objective(s): To determine the efficacy of adjuvant nonspecific immunotherapy to standard alkylating agent therapy in patients with Stage III optimal carcinoma of the ovary.

Technical Approach: Patients in "optimal" category (3 cm or less greatest diameter of residual tumor(s) with proven primary Stage III epithelial cancer of the ovary) who have undergone tumor-reductive surgery will be included in the study.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient remains on the study and continues to respond to therapy. This study has been closed to new entries.

Detail Summary Sheet

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|---|-----------------|-----------------|
| Date: 1 Nov 84 | Proj No: GOG 26 | Status: Ongoing |
| Title: Master Protocol for Phase II Drug Studies in Treatment of Advanced, Recurrent Pelvic Malignancies. | | |

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| Start Date FY 78 Principal Investigator Danny R. Barnhill, M.D., MAJ, MC Dept/Svc Department of Obstetrics-Gynecology Key Words: Malignancy, pelvic | Est Comp Date: Facility Brooke Army Medical Center Associate Investigators: |
| Accumulative MEDCASE Cost: Number of Subjects Enrolled During Reporting Period: Total Number of Subjects Enrolled to Date: Date of Periodic Review _____ | Est Accumulative OMA Cost: Results _____ |

Objective(s): This protocol constitutes a Phase II design outlining the procedures that will be performed to screen for activity of new agents or drug combinations in patients with advanced recurrent pelvic malignancies. Its intent is to determine the efficacy of chemotherapeutic agents in patients whose advanced malignancies have been resistant to high priority methods of treatment.

Technical Approach: This is a study of multiple chemotherapeutic agents. Therapy will follow the schema outlined in the study protocol.

Progress: This study remains open for the study of new Phase II drugs. No patients have been entered.

Detail Summary Sheet

Date: 1 Nov 84 Proj No: GOG 34 Status: Ongoing
 Title: A Randomized Study of Adriamycin as an Adjuvant After Surgery and Radiation Therapy in Patients with High Risk Endometrial Carcinoma, Stage I, and Occult Stage II.

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|--|--|
| Start Date FY 78 | Est Comp Date: |
| Principal Investigator Danny R. Barnhill, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Obstetrics-Gynecology | Associate Investigators: |
| Key Words: Carcinoma, endometrial | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 2 | |
| Date of Periodic Review | Results |

Objective(s): To study differences in morbidity and patient survival as functions of various tumor growth patterns as well as treatments.

Technical Approach: All patients with primary, previously untreated, histologically confirmed invasive carcinoma of the endometrium Stage I and Stage II occult, all grades, with one or more of the following high risk criteria are eligible: (1) all lesions equal to or greater than one-half myometrial involvement; (2) positive pelvic and/or para-aortic nodes; (3) microscopic evidence of cervical involvement but no gross clinical involvement of the cervix. The following types of histologically confirmed uterine carcinoma are eligible: adenocarcinoma, adenoacanthoma, adenosquamous carcinoma.

Therapy will follow the schema outlined in the study protocol.

Technical Approach: Two patients remain on the study and are responding well.

Detail Summary Sheet

Date: 1 Nov 84 Proj No: GOG 36 Status: Closed
Title: Surgical-Pathologic Study of Women with Squamous Cell Carcinoma of the Vulva.

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| <u>Start Date</u> FY 78 | <u>Est Comp Date:</u> |
| <u>Principal Investigator</u> | <u>Facility</u> |
| <u>Danny R. Barnhill, M.D., MAJ, MC</u> | <u>Brooke Army Medical Center</u> |
| <u>Dept/Svc</u> | <u>Associate Investigators:</u> |
| <u>Department of Obstetrics-Gynecology</u> | |
| <u>Key Words:</u> | |
| <u>Carcinoma, vulva</u> | |
| <u>Accumulative MEDCASE Cost:</u> | <u>Est Accumulative OMA Cost:</u> |
| <u>Number of Subjects Enrolled During Reporting Period:</u> _____ | |
| <u>Total Number of Subjects Enrolled to Date:</u> _____ | |
| <u>Date of Periodic Review</u> | <u>Results</u> |

Objective(s): To determine the validity of current FIGO staging to the histopathologic prognostic factors of size of lesion, location of lesion, depth of invasion of tumor in millimeters, histologic grade, and site and number of positive lymph nodes in Stage I-IV carcinoma of the vulva.

Technical Approach: All patients with primary, previously untreated, histologically confirmed, invasive squamous cell carcinoma of the vulva clinically determined to be Stage I through IV are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients were entered on this study. The study has been closed by COG.

Detail Summary Sheet

| | | |
|--|-----------------|----------------|
| Date: 1 Nov 84 | Proj No: GOG 37 | Status: Closed |
| Title: Randomized Study of Radiation Therapy vs Pelvic Node Resection for Patients with Invasive Squamous Cell Carcinoma of the Vulva Having Positive Groin Nodes. | | |

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|--|----------------------------|
| Start Date FY 78 | Est Comp Date: |
| Principal Investigator | Facility |
| Danny R. Barnhill, M.D., MAJ, MC | Brooke Army Medical Center |
| Dept/Svc | Associate Investigators: |
| Department of Obstetrics-Gynecology | |
| Key Words: | |
| Carcinoma, vulva | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): To determine the benefit and morbidity of adding adjunctive radiation therapy to pelvis and groin for patients with positive groin nodes at radical vulvectomy and bilateral groin dissection.

Technical Approach: All patients with primary, previously untreated, histologically confirmed squamous cell carcinoma of the vulva such that radical vulvectomy suffices to remove all of the local lesion and whose surgery revealed that there were nodes in the groin on one or both sides containing metastatic carcinoma are eligible.

Progress: No patients were entered on this study. The study has been closed by GOG.

Detail Summary Sheet

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| Date: 1 Nov 84 | Proj No: GOG 40 | Status: Ongoing |
| Title: A Clinical-Pathologic Study of Stage I and II Uterine Sarcomas. | | |

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| Start Date FY 79 | Est Comp Date: |
| Principal Investigator Danny R. Barnhill, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc <u>Department of Obstetrics-Gynecology</u> | Associate Investigators: |
| Key Words: Sarcoma, uterine | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): To determine the incidence of pelvic and aortic lymph node metastases associated with Stage I and II uterine sarcomas, the relationship of these node metastases to other important prognostic factors such as mitotic index of the tumor, and the complication rate of the procedures.

Technical Approach: All patients with histologically proven uterine sarcoma clinical Stage I and II who are medically suitable for hysterectomy and lymphadenectomy are eligible for the study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

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|--|------------------------|------------------------|
| <u>Date:</u> 1 Nov 84 | <u>Proj No:</u> GOG 41 | <u>Status:</u> Ongoing |
| <u>Title:</u> Surgical Staging of Ovarian Carcinoma. | | |

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|---|---------------------------------|
| <u>Start Date FY 79</u> | <u>Est Comp Date:</u> |
| <u>Principal Investigator</u> | <u>Facility</u> |
| Danny R. Barnhill, M.D., MAJ, MC | Brooke Army Medical Center |
| <u>Dept/Svc</u> | <u>Associate Investigators:</u> |
| Department of Obstetrics-Gynecology | |
| <u>Key Words:</u> | |
| Carcinoma, ovarian | |
| <u>Accumulative MEDCASE</u> | <u>Est Accumulative</u> |
| <u>Cost:</u> | <u>OMA Cost:</u> |
| <u>Number of Subjects Enrolled During Reporting Period:</u> _____ | |
| <u>Total Number of Subjects Enrolled to Date:</u> 1 | |
| <u>Date of Periodic Review</u> | <u>Results</u> |

Objective(s): 1) To determine the spread of ovarian carcinoma in intraperitoneal structures and retroperitoneal lymph nodes by direct examination, cytologic sampling, and biopsy.

- 2) To establish a surgical protocol for patients entered into GOG ovarian cancer treatment protocols.
- 3) To determine the complication rate of the procedures.

Technical Approach: Patients with all histologic types of primary ovarian cancer are eligible, including epithelial tumors, germ cell tumors, stromal tumors, and all others. Patients must be entered within two weeks of the last surgery.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient entered on this study continues to do well.

Detail Summary Sheet

Date: 1 Nov 84 Proj No: GOG 42 Status: Closed
 Title: Treatment of Recurrent or Advanced Uterine Sarcoma. A Randomized Comparison of Adriamycin vs Adriamycin and Cyclophosphamide, Phase III.

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|--|--|
| Start Date FY 79 | Est Comp Date: |
| Principal Investigator Danny R. Barnhill, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc <u>Department of Obstetrics-Gynecology</u> | Associate Investigators: |
| Key Words: Sarcoma, uterine | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): 1) To determine if Adriamycin alone is more effective than Adriamycin and Cyclophosphamide in producing responses in advanced or recurrent uterine sarcoma.

2) To determine the duration of response for each different treatment arm.

Technical Approach: Patients with primary Stage III, primary Stage IV or recurrent uterine sarcoma are eligible. Both patients with measurable and non-measurable disease are eligible, but they will be analyzed separately. Patients with all cell types of uterine sarcoma are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study. The study has been closed by GOG.

Detail Summary Sheet

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|--|-----------------|----------------|
| Date: 1 Nov 84 | Proj No: GOG 43 | Status: Closed |
| Title: A Randomized Comparison of Cis-Platinum 50mg/m ² IV Every 3 Weeks vs Cis-Platinum 100mg/m ² IV Every 3 weeks vs Cis-Platinum 20mg/m ² IV Daily x 5 Days in Treatment of Patients with Advanced Carcinoma of the Cervix, Phase III. | | |

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| Start Date FY 79 | Est Comp Date: |
| Principal Investigator Danny R. Barnhill, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc <u>Department of Obstetrics-Gynecology</u> | Associate Investigators: |
| Key Words: Carcinoma, cervix | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review | Results |

Objective(s): 1) To confirm the effectiveness of cis-platinum (DDP) in advanced and recurrent squamous cell carcinoma of the cervix no longer responding to radiation therapy or surgery.

2) To compare the frequency and duration of response and adverse effects of DDP therapy using three different doses and treatment schedules.

3) To evaluate the roles of serial determination of serum carcinoembryonic antigen (CEA) levels in determining extent of disease, response to treatment, and in predicting treatment failure.

Technical Approach: Eligible patients must have histologically confirmed, locally advanced, recurrent, persistent, or metastatic squamous cell carcinoma of the cervix which is resistant to curative treatment with surgery or radiotherapy. All patients must have lesions which are measurable or evaluable by physical examination. Patients will have recovered from effects of recent surgery or radiotherapy, and will be free of clinically significant infection.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient entered on this study continues to do well. The study has been closed by GOG.

Detail Summary Sheet

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|---|-----------------|-----------------|
| Date: 1 Nov 84 | Proj No: GOG 44 | Status: Ongoing |
| Title: Evaluation of Adjuvant Vincristine, Dactinomycin, and Cyclophosphamide Therapy in Malignant Germ Cell Tumors of the Ovary After Resection of All Gross Tumor, Phase III. | | |

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| Start Date FY 79 | Est Comp Date: |
| Principal Investigator Danny R. Barnhill, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Obstetrics-Gynecology | Associate Investigators: |
| Key Words: Germ cell tumor | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): 1) To evaluate the effect of combine prophylactic vincristine, dactinomycin, and cyclophosphamide chemotherapy in patients with endodermal sinus tumor, embryonal carcinoma, immature teratoma (Grades 2 and 3), choriocarcinoma, and malignant mixed germ cell tumors of the ovary, Stages I and II after total removal of all gross tumor.

- 2) To evaluate the role of serum markers, especially alpha-fetoprotein (AFP) and human chorionic gonadotropin (beta HCG), when these are present, in predicting response and relapse.
- 3) To determine the role of restaging laparotomy in determining response, predicting relapse and planning further therapy.

Technical Approach: Patients with histologically confirmed malignant germ cell tumors of the ovary, Stage I or II, if previously untreated and completely resected, excluding patients with pure dysgerminoma unless classified as anaplastic, or eligible. Patients with grade 2 or 3 immature teratoma are also eligible. Patients with early Stage III disease will be accepted if all gross tumor is resected.

Therapy will follow the schema outlines in the study protocol.

Progress: No patients have been registered on this protocol.

Detail Summary Sheet

Date: 1 Nov 84 Proj No: GOG 45 Status: Ongoing
Title: Evaluation of Vinblastine, Bleomycin, and Cis-Platinum in Stage III and IV and Recurrent Malignant Germ Cell Tumors of the Ovary, Phase III.

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| Start Date FY 79 | Est Comp Date: |
| Principal Investigator Danny R. Barnhill, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Obstetrics-Gynecology | Associate Investigators: |
| Key Words: Germ cell tumor | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: _____ | |
| Total Number of Subjects Enrolled to Date: _____ | |
| Date of Periodic Review | Results |

Objective(s): To evaluate the effect of four cycles of combined Vinblastine, Bleomycin, and Cis-Platinum (VBP) chemotherapy in the management of patients with endodermal sinus tumor, embryonal carcinoma, immature teratoma (all grades), choriocarcinoma, and malignant germ cell tumors of the ovary with advanced or recurrent disease, incompletely resected.

Technical Approach: Patients with histologically confirmed malignant germ cell tumors of the ovary with advanced (Stage III-IV) or recurrent disease, incompletely resected, excluding patients with pure dysgerminoma (mature or anaplastic) are eligible. Patients with incompletely resected Stage II disease and patients previously treated with Vinblastine, Dactinomycin and Cyclophosphamide are also eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study.

Detail Summary Sheet

| | | |
|--|-----------------|----------------|
| Date: 1 Nov 84 | Proj No: GOG 46 | Status: Closed |
| Title: A Randomized Comparison of Melphalan vs Intraperitoneal Chromic Phosphate in the Treatment of Women with Stage I (Exclusive of Stage IA(i) G1 and IB(i) G1) Epithelial Carcinoma of the Ovary, Phase III. | | |

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|--|--|
| Start Date FY 79 | Est Comp Date: |
| Principal Investigator Danny R. Barnhill, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Obstetrics-Gynecology | Associate Investigators: |
| Key Words: Carcinoma, ovary | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review | Results |

Objective(s): To evaluate the relative effectiveness of Melphalan vs intraperitoneal Chromic Phosphate as adjuvant therapy in Stage I exclusive of Stage IA(i) G1 and Stage IB(i) G1 epithelial cancers of the ovary in a randomized prospective study.

Technical Approach: Patients with surgical Stage IA(i) G2, G3; IA(ii); IB(i) G2, G3; IB(ii), and IC epithelial cancer of the ovary who have undergone optimal staging described in GOG 41 are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient enrolled on this study continues to do well. The study has been closed by GOG.

Detail Summary Sheet

| | | |
|---|-----------------|----------------|
| Date: 1 Nov 84 | Proj No: GOG 47 | Status: Closed |
| Title: A Randomized Study of Adriamycin + Cyclophosphamide vs Adriamycin + Cyclophosphamide + Cis-Platinum in Patients with Advanced Ovarian Adenocarcinoma Suboptimal Stage II, Stage IV and Recurrent, Phase III. | | |

| | |
|--|----------------------------|
| Start Date FY 80 | Est Comp Date: |
| Principal Investigator | Facility |
| Danny R. Barnhill, M.D., MAJ, MC | Brooke Army Medical Center |
| Dept/Svc | Associate Investigators: |
| Department of Obstetrics-Gynecology | |
| Key Words: | |
| Adenocarcinoma, ovary | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | 0 |
| Total Number of Subjects Enrolled to Date: | 0 |
| Date of Periodic Review | Results |

Objective(s): 1) To determine if the addition of Cis-Platinum to Adriamycin plus Cyclophosphamide improves remission rate, remission duration or survival in Stage IV, suboptimal Stage III, and recurrent ovarian adenocarcinoma.

2) To determine the frequency and duration of true complete remission using these regimens as judged at second-look laparotomy.

Technical Approach: Patients who have been diagnosed as Stage IV and suboptimal Stage III primary cases together with all recurrent cases are eligible. Both patients with measurable disease and patients without measurable disease, as a separate category, will be evaluated.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has been closed by GOG.

Detail Summary Sheet

Date: 1 Nov 84 Proj No: GOG 48 Status: Ongoing
Title: A Study of Progestin Therapy and a Randomized Comparison of Adriamycin vs Adriamycin + Cyclophosphamide in Patients with Advanced Endometrial Carcinoma After Hormonal Failure, Phase III.

| | |
|---|---|
| <u>Start Date</u> FY 80 | <u>Est Comp Date:</u> |
| <u>Principal Investigator</u> Danny R. Barnhill, M.D., MAJ, MC | <u>Facility</u> Brooke Army Medical Center |
| <u>Dept/Svc</u> <u>Department of Obstetrics-Gynecology</u> | <u>Associate Investigators:</u> |
| <u>Key Words:</u> Carcinoma, endometrial | |
| <u>Accumulative MEDCASE Cost:</u> | <u>Est Accumulative OMA Cost:</u> |
| <u>Number of Subjects Enrolled During Reporting Period:</u> _____ | |
| <u>Total Number of Subjects Enrolled to Date:</u> _____ | |
| <u>Date of Periodic Review</u> | <u>Results</u> |

Objective(s): 1) To evaluate the response of advanced or recurrent endometrial carcinoma to oral progestins in patients who have received no prior hormonal therapy.

2) To compare a combination of adriamycin and cyclophosphamide to adriamycin alone as therapy for advanced or recurrent endometrial carcinoma which no longer responds to or has failed to respond to progestins in patients who have received no prior cytotoxic drugs.

Technical Approach: To be eligible for entry on this study, all patients must have documented primary Stage III, primary Stage IV, recurrent or residual endometrial adenocarcinoma, adenoacanthoma or adenosquamous carcinoma. Those patients with positive cytology as evidence of spread are eligible as non-measurable disease cases.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

| | | |
|--|-----------------|-----------------|
| Date: 1 Nov 84 | Proj No: GOG 49 | Status: Ongoing |
| Title: A Surgical-Pathologic Study of Women with Invasive Carcinoma of the Cervix Stage IB and Randomly Assigned Radiation Therapy versus no Further Therapy in Selected Patients. | | |

| | |
|--|--|
| Start Date FY 81 | Est Comp Date: |
| Principal Investigator Danny R. Barnhill, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Obstetrics-Gynecology | Associate Investigators: |
| Key Words: Carcinoma, cervix | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): 1) To determine by observations of the 5-year survival and disease-free interval, the validity of current FIGO staging to the histopathologic prognostic factors of size of lesion, location of lesion, depth of invasion of tumor, histology and grade, growth pattern, and site and number of positive lymph nodes in Stage IB carcinoma of the cervix.

- 2) To rapidly accumulate prospectively significant surgical pathologic data which would expedite development of further protocols.
- 3) To determine morbidity of primary radical surgical therapy.
- 4) To determine if radiation therapy will improve survival in selected patients with positive nodes.

Technical Approach: All patients with primary, previously untreated, histologically confirmed, invasive carcinoma of the cervix (squamous cell, adenocarcinoma and adenosquamous) are eligible. Patients must have had a pelvic and para-aortic lymphadenectomy.

Progress: No patients have been registered on this study.

Detail Summary Sheet

| | | |
|---|-----------------|----------------|
| Date: 1 Nov 84 | Proj No: GOG 50 | Status: Closed |
| Title: A Study of Adriamycin as Postoperative Therapy for Ovarian Sarcoma, Primary or Recurrent, with No Prior Chemotherapy, Phase III. | | |

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|--|--|
| Start Date FY 81 | Est Comp Date: |
| Principal Investigator Danny R. Barnhill, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Obstetrics-Gynecology | Associate Investigators: |
| Key Words: Sarcoma, ovarian | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): 1) To evaluate the efficacy of Adriamycin in the treatment of ovarian sarcomas, primary or recurrent, through historic controls.
 2) To accumulate additional surgical-pathological data relative to ovarian sarcomas.

Technical Approach: All patients must have histologically confirmed primary Stage I-IV or recurrent ovarian sarcomas. Optimal reductive surgery is required for cases with advanced disease, whether primary or recurrent. Patients may have measurable disease, non-measurable disease or no residual disease post-operatively. The endometrium must be examined to exclude an endometrial origin of tumor.

Patients with primary Stage I-IV disease must be entered and protocol therapy begun within six weeks of surgery. Patients with recurrent disease must be entered and protocol therapy begun within six weeks of documented recurrence.

Progress: No patients have been entered on this study. The protocol has been closed by GOG.

Detail Summary Sheet

| | | |
|---|----------------------------|----------------|
| Date: 1 Nov 84 | Proj No: GOG 51 | Status: Closed |
| Title: A Randomized Comparison of Droperidol versus THC in the Treatment of Nausea and Vomiting Produced by Cis-Platinum Chemotherapy for Gynecologic Malignancies. | | |
| Start Date FY 81 | Est Comp Date: | |
| Principal Investigator | Facility | |
| Danny R. Barnhill, M.D., MAJ, MC | Brooke Army Medical Center | |
| Dept/Svc | Associate Investigators: | |
| Department of Obstetrics-Gynecology | | |
| Key Words: | | |
| Accumulative MEDCASE | Est Accumulative | |
| Cost: | OMA Cost: | |
| Number of Subjects Enrolled During Reporting Period: _____ | | |
| Total Number of Subjects Enrolled to Date: _____ | | |
| Date of Periodic Review | Results _____ | |

Objective(s): To evaluate the effectiveness of Droperidol and THC as anti-emetic agents in chemotherapy of gynecologic malignancies treated with Cis-Platinum.

Technial Approach: Patients with gynecologic malignancies who receive Cis-Platinum as a single agent are eligible. Patient will be randomized to one of two treatment groups. Group 1 will receive THC by mouth during two courses of chemotherapy, and then take droperidol by injection for two chemotherapy courses. Group 2 will receive droperidol by injection for two chemotherapy courses and then THC by mouth during two courses of chemotherapy.

Progress: No patients were enrolled on this study. The study has been closed by GOG.

Detail Summary Sheet

| | | |
|----------------|-----------------|-----------------|
| Date: 1 Nov 84 | Proj No: GOG 52 | Status: Ongoing |
|----------------|-----------------|-----------------|

Title: A Phase III Randomized Study of Cyclophosphamide plus Adriamycin plus Platinol (Cis-Platinum) vs Cyclophosphamide Platinol in Patients with Optimal Stage III Ovarian Adenocarcinoma.

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|--|--|
| Start Date FY 81 | Est Comp Date: |
| Principal Investigator Danny R. Barnhill, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Obstetrics-Gynecology | Associate Investigators: |
| Key Words: Adenocarcinoma, ovary | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: 2 | |
| Date of Periodic Review | Results |

Objective(s): To determine in "optimal" Stage III ovarian adenocarcinoma, if the addition of adriamycin to cyclophosphamide plus platinol improves progression-free interval, frequency of negative second-look laparotomy and survival.

Technical Approach: Patients with proven primary Stage III ovarian adenocarcinoma (serous, mucinous, endometrioid, undifferentiated carcinoma, mixed epithelial carcinoma or clear cell) confined to the abdominal cavity and its peritoneal surfaces with residual tumor masses after surgery no larger than 1 cm in diameter are eligible. Entry must be no more than six weeks postoperative.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patients entered on this study continue to do well.

Detail Summary Sheet

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|----------------|-----------------|-----------------|
| Date: 1 Nov 84 | Proj No: GOG 56 | Status: Ongoing |
|----------------|-----------------|-----------------|

Title: A Randomized Comparison of Hydroxyurea vs Misonidazole as an Adjunct to Radiation Therapy in Patients with Stages IIB, III, and IVA Carcinoma of the Cervix and Negative Para-Aortic Nodes.

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|--|--|
| Start Date Nov 81 | Est Comp Date: |
| Principal Investigator Danny R. Barnhill, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Obstetrics-Gynecology | Associate Investigators: |
| Key Words: Carcinoma, cervix | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): 1) To determine whether hydroxyurea or misonidazole is superior as a potentiation of radiation therapy in advanced cervical cancer.

2) To compare the toxicity of hydroxyurea vs misonidazole when given concurrently with radiotherapy.

Technical Approach: All patients with primary, previously untreated histologically confirmed invasive squamous cell carcinoma of the uterine cervix, clinical stages IIB through IVA confined to the pelvis, will be eligible for this study

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled in this study.

Detail Summary Sheet

Date: 1 Nov 84 Proj No: GOG 59 Status: Ongoing
 Title: A Randomized Comparison of Extended Field Radiation Therapy and Hydroxyurea Followed by Cisplatin or No Further Therapy in Patients with Cervical Squamous Cell Carcinoma Metastatic to High Common Iliac...Lymph Nodes, Phase III.

| | |
|--|--|
| Start Date Nov 81 | Est Comp Date: |
| Principal Investigator Danny R. Barnhill, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Obstetrics-Gynecology | Associate Investigators: |
| Key Words: Carcinoma, cervix | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): To determine if cis-diamminedichloroplatinum, cisplatin, given in an adjuvant setting will decrease the risk of geographic failure or improve the survival rate of progress-free interval in patients with squamous carcinoma of the cervix with metastases to high common iliac and/or para-aortic lymph nodes, proven by either histologic or cytologic means.

Technical Approach: All patients with primary, previously untreated, histologically confirmed, invasive squamous cell carcinoma of the uterine cervix, all clinical stages, with metastasis to high common iliac or para-aortic lymph nodes proven by cytologic or histologic means are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study.

Detail Summary Sheet

| | | |
|--|------------------------|------------------------|
| Date: 1 Nov 84 | Proj No: GOG 60 | Status: Ongoing |
| Title: A Randomized Study of Doxorubicin plus Cyclophosphamide plus Cisplatin vs Doxorubicin plus Cyclophosphamide plus Cisplatin plus BCG in Patients with Advanced Suboptimal Ovarian Adenocarcinoma, Stage III and IV. | | |

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| Start Date Nov 81 | Est Comp Date: |
| Principal Investigator | Facility |
| Danny R. Barnhill, M.D., MAJ, MC | Brooke Army Medical Center |
| Dept/Svc | Associate Investigators: |
| Department of Obstetrics-Gynecology | |
| Key Words: | |
| Adenocarcinoma, ovary | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: _____ | |
| Total Number of Subjects Enrolled to Date: _____ | |
| Date of Periodic Review _____ | Results _____ |

Objective(s): 1) To determine if the addition of BCG to doxorubicin (adriamycin) plus cyclophosphamide plus cisplatin improves remission rate, remission duration or survival in suboptimal Stage III and IV ovarian adenocarcinoma.

2) To determine the frequency and duration of true complete remission using these regimens as judged at second-look laparotomy.

Technical Approach: Patients with established suboptimal Stage III and IV ovarian epithelial cancer are eligible. All patients must have optimal surgery and appropriate tissue for histologic evaluation, as detailed in protocol GOG 41.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

| | | |
|---|-----------------|-----------------|
| Date: 1 Nov 84 | Proj No: GOG 61 | Status: Ongoing |
| Title: Randomized Study of Cis-platinum + Cyclophosphamide vs Hexamethylmelamine after Second-Look Surgery in Nonmeasurable Stage III Ovarian Adenocarcinoma Partially Responsive to...Cis-platinum and Cyclophosphamide. | | |

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|--|--|
| Start Date Nov 81 | Est Comp Date: |
| Principal Investigator Danny R. Barnhill, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Obstetrics-Gynecology | Associate Investigators: |
| Key Words: Adenocarcinoma, ovary | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): To determine, in nonmeasurable but residual Stage III ovarian adenocarcinoma partially responsive after treatment with regimens containing cis-platinum and cyclophosphamide, if the progression-free interval and survival are improved by continuing cyclophosphamide plus cisplatin or by changing treatment to hexamethylmelamine.

Technical Approach: Patients who have been diagnosed as Stage III ovarian cancer and who have had residual disease found at second-look laparotomy may be eligible. A patient who began with measurable disease and achieved a clinical complete response, but then at second look was found to have residual disease after treatment with regimens containing cis-platinum plus cytoxan would be eligible. A patient who originally had nonmeasurable disease and who at the time of second look has less volume of disease than was described at the time of the original surgery or in whom there has been no change in the volume of disease would be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study.

Detail Summary Sheet

| | | |
|---|-----------------|-----------------|
| Date: 2 Nov 84 | Proj No: GOG 70 | Status: Ongoing |
| Title: A Randomized Comparison of Single-Agent Chemotherapy, Methotrexate and Methotrexate with Folinic Acid Rescue, in "Good Prognosis" Metastatic Gestational Trophoblastic Disease, Phase III. | | |

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| Start Date 25 Sep 84 | Est Comp Date: |
| Principal Investigator Danny R. Barnhill, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Obstetrics-Gynecology | Associate Investigators: |
| Key Words: Trophoblastic disease | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): 1) To judge the relative efficacy of scheduling variation in the chemotherapeutic management of "good prognosis" metastatic trophoblastic disease.

2) To ascertain the relative toxicities of the two regimens.

Technical Approach: To be eligible for this study, patients must have metastatic gestational trophoblastic disease who are "good prognosis" with: 1) antecedent molar pregnancy, ectopic pregnancy, or abortion; 2) duration of disease less than 4 months from antecedent pregnancy; 3) metastatic disease present but no liver or brain metastasis. All patients must have had pelvic ultrasound to exclude intrauterine pregnancy.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

| | | |
|----------------|-----------------|-----------------|
| Date: 2 Nov 84 | Proj No: GOG 72 | Status: Ongoing |
|----------------|-----------------|-----------------|

Title: Ovarian Tumors of Low Malignant Potential: A Study of the Natural History and a Phase II Trial of Melphalan and Secondary Treatment with Cisplatin.

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|--|--|
| Start Date 25 Sep 84 | Est Comp Date: |
| Principal Investigator Danny R. Barnhill, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc <u>Department of Obstetrics-Gynecology</u> | Associate Investigators: |
| Key Words: Cancer, ovary | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: _____ | |
| Total Number of Subjects Enrolled to Date: _____ | |
| Date of Periodic Review _____ | Results _____ |

Objective(s): 1) To evaluate the biologic behavior of ovarian tumors of low malignant potential.

- 2) To evaluate the effectiveness of chemotherapy against this disease; initially, a Phase II study of melphalan.
- 3) To evaluate the response rate to cisplatin in melphalan failures.

Technical Approach: All patients with ovarian tumors considered to be in the pathology classification of low malignancy potential are eligible. Patients must have undergone adequate surgical staging and any stage of disease from I-IV inclusive.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

Date: 2 Nov 84 Proj No: GOG 78 Status: Ongoing
Title: Evaluation of Adjuvant Vinblastine, Bleomycin and Cisplatin Therapy in
Totally Resected Choriocarcinoma, Endodermal Sinus Tumor, or Embryonal Carcinoma
of the Ovary.

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|---|-----------------------------------|
| <u>Start Date 25 Sep 84</u> | <u>Est Comp Date:</u> |
| <u>Principal Investigator</u> | <u>Facility</u> |
| <u>Danny R. Barnhill, M.D., MAJ, MC</u> | <u>Brooke Army Medical Center</u> |
| <u>Dept/Svc</u> | <u>Associate Investigators:</u> |
| <u>Department of Obstetrics-Gynecology</u> | |
| <u>Key Words:</u> | |
| <u>Carcinoma, ovary</u> | |
| <u>Accumulative MEDCASE</u> | <u>Est Accumulative</u> |
| <u>Cost:</u> | <u>OMA Cost:</u> |
| <u>Number of Subjects Enrolled During Reporting Period:</u> _____ | |
| <u>Total Number of Subjects Enrolled to Date:</u> _____ | |
| <u>Date of Periodic Review</u> | <u>Results</u> |

Objective(s): 1) To evaluate the effect of adjuvant vinblastine, bleomycin, and cisplatin (VBP) chemotherapy in patients with endodermal sinus tumor and choriocarcinoma of the ovary (pure and mixed) after removal of all gross tumor.

2) To evaluate the role of serum markers, especially alpha fetoprotein (AFP), and human chorionic gonadotropin (HCG) when these are present initially in predicting recurrence.

3) To evaluate the role of reassessment laparotomy in determining response, detecting early relapse and planning further therapy.

4) To compare the biologic behavior of pure endodermal sinus tumors with mixed germ cell tumors containing endodermal sinus elements.

Technical Approach: Patients with histologically confirmed Stage I choriocarcinoma, endodermal sinus tumor or embryonal carcinoma of the ovary, pure or mixed with other elements, if totally resected are eligible. Patients with Stage II and Stage III disease are also eligible if all gross tumor has been resected. The serum AFP and beta-HCG levels should be normal or falling at a rate that does not suggest residual disease.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

| | | |
|--|---------------|----------------|
| Date: 1 Nov 84 | Proj No: 7601 | Status: Closed |
| Title: Ovarian Cancer Study Group Protocol for Selected Stage IAI - IBI Ovarian Cancer (Well and Moderately Differentiated). | | |

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|--|--|
| Start Date FY 79 | Est Comp Date: |
| Principal Investigator Danny R. Barnhill, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc <u>Department of Obstetrics-Gynecology</u> | Associate Investigators: |
| Key Words: Cancer, ovary | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): 1) To define the natural history (relapse rate, relapse site, relapse free survival) of patients treated by surgery alone.

2) To study determine whether prophylactic, adjuvant chemotherapy with melphalan alters the the natural history.

Technical Approach: All eligible patients must hve a histopathologic diagnosis of common epithelial ovarian cancer of one of the following types: serous, mucinous, and those listed in Appendix I of the protocol. After definitive staging procedure, if the patient is a selective Stage IAI or IBI, and the histologic grade is well or moderately differentiated, the patient is eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been registered on this study. The study has been closed to new entries by GOG.

Detail Summary Sheet

| | | |
|---|---------------|----------------|
| Date: 1 Nov 84 | Proj No: 7602 | Status: Closed |
| Title: Ovarian Cancer Study Group Protocol for All Stage IC and II (A,B,C) and Selected Stage IAii and IBii Ovarian Cancer. | | |

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| Start Date FY 79 | Est Comp Date: |
| Principal Investigator Danny R. Barnhill, M.D., MAJ, MC | Facility Brooke Army Medical Center |
| Dept/Svc <u>Department of Obstetrics-Gynecology</u> | Associate Investigators: |
| Key Words: Cancer, ovary | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): 1) To define the natural history (relapse rate, relapse sites, relapse free survival, regression rate, duration of regression) of patients treated by surgery plus either chemotherapy or chemotherapy plus radiation therapy.

2) To study the effect of various potential prognostic factors (stratification factors) on the natural history of patients treated by each form of therapy.

Technical Approach: All eligible patients must have a histopathologic diagnosis of common epithelial ovarian cancer of one of the following types: serous, mucinous or one of the types identified in Appendix I of the study protocol. After a definitive staging procedure, if the patient is Stage II-A, II-B, II-C, I-Aii, I-Bii, or I-Ai or I-Bi with poorly differentiated tumors, she is eligible for the study. The patient must have had no previous treatment except surgical therapy.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: No patients were entered on this study. The study has been closed by COG.

Detail Summary Sheet

| | | |
|---|-------------------|----------------|
| Date: 6 Nov 84 | Proj No: POG 7376 | Status: Closed |
| Title: Evaluation of Natural History of Histiocytosis X in Childhood. | | |

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|--|--|
| Start Date Feb 81 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Histiocytosis X | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review | Results |

Objective(s): To obtain information about the natural history of all forms of histiocytosis X and histiocytic medullary reticulosis.

Technical Approach: All new patients with a biopsy-proven diagnosis of histiocytosis X should be registered on this study.

The study involves reporting on the results of examinations, tests, and treatment during the course of the disease. The examinations and tests are as outlined in the study protocol.

Progress: One patient has been registered on the study. The study has been closed to new entries by the Pediatric Oncology Group.

Detail Summary Sheet

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|---|-------------------|----------------|
| Date: 6 Nov 84 | Proj No: POG 7612 | Status: Closed |
| Title: MOPP + Bleo vs A-COPP with IF RT in Stage III Hodgkin's Disease in Children. | | |

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|--|--|
| Start Date 25 Sep 81 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Hodgkin's disease | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review | Results |

Objective(s): 1) To compare the effectiveness of IF radiotherapy plus MOPP + Bleo with IF radiotherapy plus A-COPP chemotherapy in treating Stage III Hodgkin's disease in children.

2) To determine the patient tolerance of the two chemotherapy regimens in terms of immediate toxicity including the incidence of infection.

Technical Approach: All children, 18 years or younger, with Stage III Hodgkin's disease including extranodal presentations + constitutional symptoms, regardless of specific with no prior therapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been entered into the study. It appears that this treatment regimen is effective in controlling the disease. The study has been closed to new entries.

Detail Summary Sheet

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| Date: 6 Nov 84 | Proj No: POG 7621 | Status: Closed |
| Title: MOPP vs OPP in the Treatment of Children with Recurrent Brain Tumors. | | |

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| Start Date Feb 81 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Brain tumors | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 0 | |
| Date of Periodic Review | Results |
| Objective(s): To determine and compare response to MOPP or OPP in children with recurrent brain tumors. | |

Technical Approach: All patients who have been diagnosed as having a central nervous system tumor, and who have previously received maximally allowable dose of radiotherapy will be eligible for randomization which will require no prior therapy with either nitrogen mustard or BCNU. Patients must be 18 years of age or under at the time of diagnosis.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study. The study has been closed to new entries.

Detail Summary Sheet

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|---|-------------------|----------------|
| Date: 6 Nov 84 | Proj No: POG 7712 | Status: Closed |
| Title: Comparison of Treatment Regimens for the First CNS Relapse in Children with Acute Lymphocytic Leukemia - CNS #6. | | |

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| Start Date 25 Sep 81 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Leukemia, acute lymphocytic | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: _____ | |
| Total Number of Subjects Enrolled to Date: _____ | |
| Date of Periodic Review _____ | Results _____ |

Objective(s): To compare two therapies for CNS leukemia with respect to length of CNS remission and CNS toxicity.

Technical Approach: Patients less than 21 years of age at time of initial diagnosis with first CNS relapse who have not had more than one marrow relapse are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered into this study. The study is closed to new entries.

Detail Summary Sheet

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|--|-------------------|-----------------|
| Date: 6 Nov 84 | Proj No: POG 7799 | Status: Ongoing |
| Title: Rare Tumor Registry for Childhood Solid Tumor Malignancies. | | |

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| Start Date 25 Sep 81 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Solid tumor malignancies | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review | Results |

Objective(s): 1) To collect natural history data on malignancies which occur so rarely that large series of patients cannot be accumulated any single institution.

2) To evaluate therapies in those groups of rare tumors in which fair numbers of cases can be accrued.

Technical Approach: Any child under the age of 18 years at diagnosis with a rare solid tumor is eligible for the study.

Progress: One patient remains on this study. No reportable data are available.

Detail Summary Sheet

Date: 6 Nov 84 Proj No: POG 7829 Status: Closed
Title: Comparison of Two Dose Regimens of Intrathecal Methotrexate for CNS Leukemia, Phase II.

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| Start Date 25 Sep 81 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Leukemia | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review _____ Results _____ | |

Objective(s): To compare the toxicity, response rates and duration of response obtained by using a two dose regimen of intrathecal methotrexate.

Technical Approach: Patients under the age of 21 with CNS leukemia in relapse who are not known to be resistant to intrathecal methotrexate are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients were registered on this protocol. The study has been closed.

Detail Summary Sheet

| | | |
|---|-------------------|----------------|
| Date: 6 Nov 84 | Proj No: POG 7834 | Status: Closed |
| Title: Second Induction Maintenance in Acute Lymphocytic Leukemia, Phase III. | | |

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| Start Date 25 Sep 81 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Leukemia, acute lymphocytic | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review | Results |

Objective(s): To determine in children in the first relapse of ALL in remission duration which can be achieved following an intensive and aggressive induction regimen and maintenance.

Technical Approach: Patients under the age of 21 years in their first CNS and/or extramedullary and/or bone marrow relapse with acute lymphocytic leukemia are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient entered on the study did not respond to the treatment regimen. The study has been closed to new entries.

Detail Summary Sheet

| | | |
|---|-------------------|-----------------|
| Date: 6 Nov 84 | Proj No: POG 7837 | Status: Ongoing |
| Title: Evaluation of Systemic Therapy for Children with T-Cell Acute Lymphatic Leukemia, Phase III. | | |

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| Start Date 25 Sep 81 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Leukemia, acute lymphatic | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 2 | |
| Total Number of Subjects Enrolled to Date: 4 | |
| Date of Periodic Review _____ | Results _____ |

Objective(s): To evaluate the effectiveness of a program of sequential systemic chemotherapy plus CNS treatment for children with untreated T-cell leukemia.

Technical Approach: Patients under the age of 21 with a diagnosis of T-cell leukemia as defined by SWOG 7865 including all patients who have 20% or greater E-rosetting leukemia cells are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Four patients have been entered on the study. All are doing well.

Detail Summary Sheet

Date: 6 Nov 84 Proj No: POG 7843 Status: Closed
Title: Evaluation of Rubidazone in the Treatment of Children with Solid Tumors, Phase II.

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| Start Date 25 Sep 81 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Solid tumors | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): To determine the clinical efficacy of rubidazone in the treatment of malignant tumors in children with and without previous anthracycline therapy and to determine the toxicity of this drug in children with solid tumors.

Technical Approach: All patients under the age of 21 with a measurable tumor lesion, resistant to conventional chemotherapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients were entered on this study. The study has been closed to new entries.

Detail Summary Sheet

| | | |
|--|-------------------|----------------|
| Date: 6 Nov 84 | Proj No: POG 7895 | Status: Closed |
| Title: Multimodal Therapy for Management of Primary Non-Metastatic Ewing's Sarcoma of Pelvic and Sacral Bones. | | |

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| Start Date 25 Sep 81 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Ewing's sarcoma | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): To determine the effectiveness of high dose intermittent chemotherapy to prevent local recurrence and/or metastases with surgical resection and a uniform radiation therapy regimen to control local disease.

Technical Approach: Patients with biopsy-proven localized Ewing's sarcoma with no prior chemotherapy and/or radiation therapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients were entered into this study. The study has been closed by the Pediatric Oncology Group.

Detail Summary Sheet

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|---|-------------------|-----------------|
| Date: 6 Nov 84 | Proj No: POG 7898 | Status: Ongoing |
| Title: Intergroup Study of Rhabdomyosarcoma - II. | | |

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| Start Date 5 Mar 84 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Rhabdomyosarcoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review | Results |

Objective(s): To compare two forms of treatment, the duration of disease control, and side effects of the treatment program.

Technical Approach: Patients under 21 years of age with the diagnosis of rhabdomyosarcoma (any of the four cellular types plus the special undifferentiated types and small cell mesenchymal sarcoma) or undifferentiated sarcoma, type indeterminate, are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study.

Detail Summary Sheet

Date: 6 Nov 84 **Proj No:** POG 7901 **Status:** Ongoing
Title: Rescue Therapy for Non-CNS Extramedullary Disease in Children with Acute Lymphoblastic Leukemia, Phase III

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|---|---|
| Start Date 27 Jan 83 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Leukemia, acute lymphoblastic | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: _____ | |
| Total Number of Subjects Enrolled to Date: 2 | |
| Date of Periodic Review | Results |

Objective(s): To administer effective local therapy for non-CNS extramedullary disease occurring during marrow remission or marrow relapse in children with acute lymphocytic leukemia (ALL).

Technical Approach: Children less than 21 years of age at time of diagnosis, with ALL are eligible for EMD "rescue" therapy when the diagnosis of EMD has been established.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patients remain on the study. No reportable data are available.

Detail Summary Sheet

| | | |
|---|-------------------|-----------------|
| Date: 7 Nov 84 | Proj No: POG 7909 | Status: Ongoing |
| Title: Evaluation of MOPP Adjuvant Chemotherapy in the Treatment of Localized Medulloblastoma and Ependymoma. | | |

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| Start Date May 81 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Medulloblastoma Ependymoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 1 | |
| Total Number of Subjects Enrolled to Date: 2 | |
| Date of Periodic Review | Results |

Objective(s): To evaluate the efficacy and toxicity of the MOPP adjuvant chemotherapy in the prevention of local recurrence of distant metastasis in children with localized medulloblastoma and ependymoma.

Technical Approach: Patients between 1 and 21 years (inclusive) with histologically proven medulloblastoma and ependymoma are eligible for the study.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patients have been entered into this study. Both have responded fairly well to therapy.

Detail Summary Sheet

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|---|-------------------|-----------------|
| Date: 7 Nov 84 | Proj No: POG 8000 | Status: Ongoing |
| Title: National Wilms' Tumor Study, III | | |

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| Start Date 25 Sep 81 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Wilms' tumor | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 0 | |
| Total Number of Subjects Enrolled to Date: 2 | |
| Date of Periodic Review | Results |

Objective(s): 1) To gain better understanding of Wilms' tumor by gathering detailed information regarding gross and histologic morphology.

- 2) To refine methods of treatment according to staging.
- 3) To test treatment hypotheses by randomized prospective clinical trials according to stage and histologic grade of disease.
- 4) To gather information about family cancer in an attempt to identify children and families at high risk.
- 5) To study the late consequences of successful treatment given for Wilms' tumor.

Technical Approach: Patients under the age of 15 with Wilms tumor are eligible.

Progress: Two patients remain on this study and are doing well.

Detail Summary Sheet

Date: 7 Nov 84 Proj No: POG 8002 Status: Closed
 Title: Combination Chemotherapy with Adriamycin, Cis-Platinum, Vincristine, and Cytoxin in Children with Metastatic Neuroblastoma (Stage IV).

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| Start Date 25 Sep 81 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Neuroblastoma | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): 1) To delineate the toxicity of the combination of cytoxin, vincristine, adriamycin and cis-platinum in children with metastatic neuroblastoma.
 2) To do a preliminary analysis of the therapeutic efficacy prior to consideration of this four-drug combination as front-line therapy for children with Stage IV neuroblastoma.

Technical Approach: Children from 1 to 18 years of age with biopsy-proven metastatic neuroblastoma (Stage IV) who have not had prior exposure to cis-platinum are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients were entered on this study. The study has been closed by the Pediatric Oncology Group.

Detail Summary Sheet

Date: 7 Nov 84 **Proj No:** POG 8035-6 **Status:** Ongoing
Title: Laboratory Subclassification and Evaluation of Treatment Regimens in
 Acute Lymphoid Leukemia of Childhood.

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| Start Date 27 Jan 83 | Est Comp Date: |
| Principal Investigator <u>Terry E. Pick, M.D., LTC, MC</u> | Facility <u>Brooke Army Medical Center</u> |
| Dept/Svc <u>Department of Pediatrics</u> | Associate Investigators: |
| Key Words: <u>Leukemia, lymphoid</u> | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 3 | |
| Total Number of Subjects Enrolled to Date: 11 | |
| Date of Periodic Review | Results |

Objective(s): 1) To determine if adding a high dose of a standard chemotherapy agent used in acute lymphocytic leukemia every 8 weeks and maintenance increases the chance of survival over the regular doses of standard chemotherapy drugs in the "good risk" patient.

2) To determine if one of three treatment regimens is better in treating the "poor risk" patient.

Technical Approach: Eligible patients will receive one of three treatment regimens. Regimen 1 consists of standard drugs given in the usual fashion with triple intrathecal medications given in the spinal fluid to prevent CNS leukemia for three years. Regimen 2 consists of the standard chemotherapy agents plus high dose Methotrexate pulses during maintenance with triple intrathecal medications given in consolidation, and low dose intrathecal Methotrexate given for one year. Regimen 3 consists of pulses of a variety of courses of different agents that are superimposed upon the routine maintenance therapy plus triple intrathecal medications for three years to determine if these pulses of different chemotherapy agents can improve the outcome of this high risk group.

Progress: Nine patients remain on the study and thus far seem to be responding to therapy. Two patients have expired.

Detail Summary Sheet

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| Date: 7 Nov 84 | Proj No: POG 8075 | Status: Closed |
| Title: Circulating Immune Complexes in Pediatric Malignancies. | | |

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| Start Date 25 Sep 81 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Immune complexes | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): 1) To determine the incidence of elevated levels of circulating immune complexes at diagnosis in children with neuroblastoma, osteogenic sarcoma, ALL and AML.

2) To correlate serial levels of circulating immune complexes with disease activity should significant quantities be initially detected.

Technical Approach: Newly diagnosed and staged patients under 21 years of age with neuroblastoma, osteogenic sarcoma, acute lymphocytic leukemia or acute myelogenous leukemia are eligible. Patients should not have had excisional surgery, chemotherapy or radiotherapy prior to initial serum sample.

Progress: No patients were entered on this study. This study has been closed to new entries.

Detail Summary Sheet

Date: 7 Nov 84 Proj No: POG 8080 Status: Ongoing
 Title: Classification of T-Cell Non-Hodgkin Lymphomas and Acute Leukemias into Subgroups Based on Immunologic Cell Surface Characteristics.

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| Start Date 25 Sep 84 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Lymphoma, non-Hodgkin Leukemia | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): 1) To compare marker data for T-leukemias with that from T-lymphomas to determine whether these entities represent clearly separate diseases, by immunological criteria, or whether they represent different clinical presentations of the same disease process.

2) To correlate the presence or absence of cell markers with clinical characteristics: age, sex, white count, organ involvement, etc., to determine whether any marker or immunologic T-subset may carry clinical prognostic significance.

Technical Approach: All newly diagnoses cases of acute lymphoblastic T-cell leukemia, with no previous chemotherapy, are eligible. Patients with non-Hodgkin lymphoma presenting with non-abdominal primary sites are likewise eligible.

Therapy for patients entered onto this study will be according to the Pediatric Oncology Group protocol priority.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

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| Date: 7 Nov 84 | Proj No: POG 8101 | Status: Ongoing |
| Title: Acute Nonlymphocytic Leukemia in Children, Phase III. | | |

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| Start Date 27 Dec 83 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Leukemia, nonlymphocytic | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: 2 | |
| Date of Periodic Review | Results |

Objective(s): 1) To compare the remission rate and toxicity data of an intensive 3-drug regimen for acute nonlymphocytic leukemia (ANLL), utilizing cytosine arabinoside, Daunomycin and 6-thioguanine, with that observed using an anthracycline-free induction regimen that employs an identical schedule of cytosine arabinoside, but combined with vincristine and dexamethasone. To determine the effect, if any, of the induction regimen on remission duration.

2) To accumulate clinical and laboratory data regarding features present at diagnosis of ANLL, to relate this information to the behavior of the disease(s) under treatment, and to establish the natural history of the disease.

Technical Approach: Patients under 21 years of age presenting with the diagnosis of acute leukemia other than lymphoblastic are eligible. Randomization for the induction regimen will be by disease category (AML, AMML, APL, and other). All patients with APL will be placed on the anthracycline-containing induction and maintenance arms.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

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|--|--------------------------|------------------------|
| <u>Date:</u> 7 Nov 84 | <u>Proj No:</u> POG 8104 | <u>Status:</u> Ongoing |
| <u>Title:</u> Comprehensive Care of the Child with Neuroblastoma: A Stage and Age Oriented Study, Phase III. | | |

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| <u>Start Date</u> 27 Jan 83 | <u>Est Comp Date:</u> |
| <u>Principal Investigator</u> Terry E. Pick, M.D., LTC, MC | <u>Facility</u> Brooke Army Medical Center |
| <u>Dept/Svc</u> Department of Pediatrics | <u>Associate Investigators:</u> |
| <u>Key Words:</u> Neuroblastoma | |
| <u>Accumulative MEDCASE Cost:</u> | <u>Est Accumulative OMA Cost:</u> |
| <u>Number of Subjects Enrolled During Reporting Period:</u> | |
| <u>Total Number of Subjects Enrolled to Date:</u> 3 | |
| <u>Date of Periodic Review</u> | <u>Results</u> |

Objective(s): 1) To treat the tumor according to age and stage at which the tumor was diagnosed.

2) To reduce later complications by separating by age and stage those patients that require surgery only; surgery and chemotherapy; surgery, chemotherapy, and radiation therapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Three patients remain on the study and are responding fairly well.

Detail Summary Sheet

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|--|-------------------|-----------------|
| Date: 7 Nov 84 | Proj No: POG 8106 | Status: Ongoing |
| Title: High-Dose Cyclophosphamide/High-Dose Methotrexate with Coordinated Triple Intrathecal Therapy for Stages III and IV Nonlymphoblastic Lymphoma, Phase III. | | |

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| Start Date 27 Dec 83 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Lymphoma, nonlymphoblastic | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: 2 | |
| Date of Periodic Review | Results |

Objective(s): 1) To determine complete remission rates, remission lengths and survival times for children with Murphy's Stages III and IV, diffuse nonlymphoblastic lymphomas using combination chemotherapy consisting of a vigorous prophylactic IT regimen, conventional doses of vincristine sulfate (VCR) and prednisone(Pred) and high doses of cyclophosphamide (CYT) and methotrexate (MTX) intravenously.

2) To document the toxicity and complications of this therapy.

Technical Approach: Patients under 21 years of age, newly diagnosed with Stage III or IV diffuse nonlymphoblastic lymphoma who have never received therapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

Date: 7 Nov 84 Proj No: POG 8303 Status: Ongoing

Title: Combination Chemotherapy for First Bone Marrow and/or Testicular Relapse of Childhood Acute Lymphoblastic Leukemia (ALL) During or Shortly Following Initial Continuation Therapy, Phase III.

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| Start Date 27 Dec 83 | Est Comp Date: |
| Principal Investigator <u>Terry E. Pick, M.D., LTC, MC</u> | Facility <u>Brooke Army Medical Center</u> |
| Dept/Svc <u>Department of Pediatrics</u> | Associate Investigators: |
| Key Words: Leukemia, lymphoblastic | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: _____ | |
| Total Number of Subjects Enrolled to Date: _____ | |
| Date of Periodic Review _____ | Results _____ |

Objective(s): 1) To determine if intensive early therapy with a 4-drug reinduction regimen immediately followed by consolidation therapy is more effective than reinduction regimens used in the past for patients with ALL or lymphoblastic lymphoma who relapse on or shortly following termination of initial continuation therapy.

- 2) To assess the efficacy and toxicity of continuous and alternating maintenance therapy during second remission with 2 drug pairs not used during first remission: VM-26 plus Ara-C and vincristine plus cyclophosphamide.
- 3) To determine the effectiveness and toxicity of periodic 4 drug reinduction therapy (reinforcement) throughout second remission.

Technical Approach: Patients less than 21 years of age who develop their first marrow relapse or overt clinical testicular relapse during initial continuation chemotherapy are eligible. Children with CNS relapse accompanying marrow and/or testicular relapse are also eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

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|---|--|-----------------|
| Date: 7 Nov 84 | Proj No: POG 8304 | Status: Ongoing |
| Title: SIMAL #4. Combination Chemotherapy for Remission Induction and Maintenance for: 1) Recurrent Childhood Lymphocytic Leukemia After Elective Cessation of Therapy; 2) Children with Occult Testicular Leukemia After 3 Years of Continuous Complete Remission. | | |
| Start Date 27 Jan 84 | Est Comp Date: | |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center | |
| Dept/Svc <u>Department of Pediatrics</u> | Associate Investigators: | |
| Key Words: Leukemia, lymphocytic | | |
| Accumulative MEDCASE | Est Accumulative | |
| Cost: | OMA Cost: | |
| Number of Subjects Enrolled During Reporting Period: _____ | | |
| Total Number of Subjects Enrolled to Date: _____ | | |
| Date of Periodic Review _____ | Results _____ | |

Objective(s): 1) To compare the effectiveness of two regimens of cyclic maintenance chemotherapy in children with ALL, who relapse 6 months or greater, after elective cessation of chemotherapy.

- 2) To evaluate the effectiveness of prophylactic intrathecal chemotherapy, during the second remission.
- 3) To compare the effectiveness of two regimens of cyclic maintenance chemotherapy in patients with testicular leukemia.
- 4) To determine the effectiveness of two regimens of cyclic maintenance chemotherapy in children with isolated CNS relapse.

Technical Approach: Patients less than 21 years of age with pathologic verification of leukemic relapse at any site more than six months after elective cessation of initial therapy are eligible. Children with their first CNS relapse are also eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

Date: 6 Nov 84 Proj No: POG 8306 Status: Ongoing
Title: Study of MTX Pharmacology During ALL Maintenance Therapy.

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|--|--|
| <u>Start Date 27 Mar 84</u> | <u>Est Comp Date:</u> |
| <u>Principal Investigator</u> <u>Terry E. Pick, M.D., LTC, MC</u> | <u>Facility</u> <u>Brooke Army Medical Center</u> |
| <u>Dept/Svc</u> <u>Department of Pediatrics</u> | <u>Associate Investigators:</u> |
| <u>Key Words:</u> <u>Leukemia, acute lymphatic</u> | |
| <u>Accumulative MEDCASE</u> | <u>Est Accumulative</u> |
| <u>Cost:</u> | <u>OMA Cost:</u> |
| <u>Number of Subjects Enrolled During Reporting Period: 3</u> | |
| <u>Total Number of Subjects Enrolled to Date: 3</u> | |
| <u>Date of Periodic Review</u> | <u>Results</u> |

Objective(s): To determine whether the levels of red cell MTX and folate in patients on therapy for ALL can be correlated with remission duration.

Technical Approach: All newly diagnosed patients with acute lymphatic leukemia are eligible. Therapy will follow the schema outlined in the study protocol.

Progress: Three patients entered on the study are doing well.

Detail Summary Sheet

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|---|--------------------------|------------------------|
| Date: 7 Nov 84 | Proj No: POG 8315 | Status: Ongoing |
| Title: Laboratory Study and Subclassification of Non-Hodgkin's Lymphoma. | | |

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|---|---|
| Start Date 25 Sep 84 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Lymphoma, Non-Hodgkin's | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: _____ | |
| Total Number of Subjects Enrolled to Date: _____ | |
| Date of Periodic Review _____ | Results _____ |

Objective(s): 1) To provide a mechanism for the group wide study of biologic characteristics of lymphoma cells, by acquisition and coordination of data from reference laboratories.

2) To seek correlates of biologic characteristics, with histopathology, clinical presentation, and end results of protocol therapies.

3) To attempt the development of a comprehensive classification of childhood NHL which is both clinically and biologically relevant.

Technical Approach: Patients less than 21 years of age with tumor tissue or cells available for study who are simultaneously being entered on open, front-end POG treatment protocols for NHL are eligible for this study.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

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|--|-------------------|-----------------|
| Date: 7 Nov 84 | Proj No: POG 8319 | Status: Ongoing |
| Title: Allogeneic Bone Marrow Transplantation for Acute Lymphoblastic Leukemia in 2nd Hematologic Remission. | | |

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| Start Date 27 Mar 84 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Leukemia, lymphoblastic | |
| Accumulative MEDCASE | Est Accumulative |
| Cost: | OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): To study the feasibility of cytosine arabinoside (ara-C), used in high dosage in conjunction with fractionated total body irradiation, followed by allogeneic or syngeneic bone marrow transplantation, in achieving long-term disease-free survival of children with acute lymphoblastic leukemia in second hematologic remission.

Technical Approach: Patients less than 21 years of age with a diagnosis of ALL verified by examination of diagnostic bone marrow, who have suffered their first bone marrow relapse while on therapy with an established POG ALL frontline protocol are eligible. Patients will be in complete remission, without evidence of leukemia either in the bone marrow or extramedullary sites.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

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|--|-------------------|-----------------|
| Date: 7 Nov 84 | Proj No: POG 8336 | Status: Ongoing |
| Title: Evaluation of Response and Further Determination of Toxicity with Aziridinylbenzoquinone (AZQ) in Children and Adolescents with Malignant Solid Tumors Resistant to Standard Therapy, Phase II. | | |

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|--|--|
| Start Date 27 Jan 84 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc <u>Department of Pediatrics</u> | Associate Investigators: |
| Key Words: Solid tumors | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 1 | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review | Results |

Objective(s): 1) To evaluate the response rate and duration of response to AZQ given to children with recurrent brain and other solid tumors resistant to standard therapy.

2) To further assess the toxicity of AZQ in children.

Technical Approach: Patients under 21 years of age who have recurrent brain tumors with a measurable lesion by CT scan, or other solid tumors (with measurable lesions) resistant to standard methods of therapy, are eligible. Patients must have a life expectancy of greater than six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

Date: 6 Nov 84 Proj No: POG 8346 Status: Ongoing
Title: Comprehensive Therapy for Ewing's Sarcoma: Tailored versus Standard
Radiation Therapy, Phase III.

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|--|--|
| Start Date 27 Mar 84 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Ewing's sarcoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: 1 | |
| Total Number of Subjects Enrolled to Date: 1 | |
| Date of Periodic Review | Results |

Objective(s): To improve disease free survival in patients with Ewing's sarcoma utilizing a multidisciplinary approach.

Technical Approach: Patients with newly diagnosed, histologically verified Ewing's sarcoma are eligible. Patients must not have received previous chemotherapy or radiation therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been entered on the study. It is too early to report any significant results.

Detail Summary Sheet

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|--|-------------------|-----------------|
| Date: 7 Nov 84 | Proj No: POG 8370 | Status: Ongoing |
| Title: Evaluation of Responses and Further Determination of Toxicity of Dibromodulcitol (DBD) in Children with Solid Tumors and Recurrent Brain Tumors Unresponsive to Standard Therapy, Phase II. | | |

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| Start Date 27 Jan 84 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Solid tumors | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: 2 | |
| Date of Periodic Review Results | |

Objective(s): 1) To determine the response rate and duration of response to DBD in children with advanced malignant disease including brain tumors unresponsive to conventional therapy.

2) To further determine the toxicity of DBD in children.

Technical Approach: Children less than 21 years of age with solid tumors including brain tumors and measurable lesions not amenable to standard therapy, with a life expectancy of more than three weeks who do not have an uncontrolled serious infection and who have an adequate nutritional status are eligible for the study.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered.

Detail Summary Sheet

Date: 7 Nov 84 Proj No: POG 8461 Status: Ongoing
 Title: Protocol for Initial Induction Failures in Childhood Acute Lymphoblastic Leukemia.

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|--|--|
| Start Date 25 Sep 84 | Est Comp Date: |
| Principal Investigator Terry E. Pick, M.D., LTC, MC | Facility Brooke Army Medical Center |
| Dept/Svc Department of Pediatrics | Associate Investigators: |
| Key Words: Leukemia, lymphoblastic | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review | Results |

Objective(s): 1) To provide intensive, uniform therapy and determine toxicity, induction rate, and remission duration of this regimen.

2) To better characterize this unique subpopulation of patients with primary drug resistance by measurement of cell surface resistance associated protein and gene amplification of dihydrofolate reductase.

Technical Approach: Children and adolescents less than 21 years of age at diagnosis with acute lymphoblastic or undifferentiated leukemia meeting the criteria outlined in the protocol are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered.

END

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